



National Health (Highly Specialised Drugs Program) Special Arrangement 2021

PB 27 of 2021

made under sections 85, 85A, 88, 99 and 100 of the
National Health Act 1953

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About this compilation

This compilation

This is a compilation of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* that shows the text of the law as amended and in force on 1 July 2024 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Part 1—Preliminary

Division 1—General

1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*.
- (2) This instrument may also be cited as PB 27 of 2021.

3 Authority

This instrument is made under sections 85, 85A, 88, 99 and 100 of the *National Health Act 1953*.

5 Simplified outline of this instrument

This instrument makes a special arrangement for the supply of pharmaceutical benefits that contain highly specialised drugs for the treatment of chronic conditions.

Restrictions apply to the prescribing and supply of these benefits because of their clinical use and other special features.

The prescribing of these benefits is in most cases limited to practitioners who have undertaken particular training or are affiliated with a specialised hospital unit.

The supply of these benefits is restricted to persons who are receiving treatment by medical practitioners and authorised nurse practitioners.

These benefits will be supplied by approved suppliers (public and private hospitals, community pharmacies and certain medical practitioners).

This instrument also deals with payments for supplies of these pharmaceutical benefits.

Note: Part VII of the Act, and regulations or other instruments made for the purposes of that Part, have effect subject to this instrument (see subsection 100(3) of the Act).

6 Definitions

- Note 1: A number of expressions used in this instrument are defined in the Act, including the following:
- (a) Chief Executive Medicare;
 - (b) hospital;
 - (c) public hospital.

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- Note 2: Under subsection 4(1A) of the Act, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning that it would have if used in that Act. Expressions used in this instrument that are defined in that Act include the following:
- (a) eligible person;
 - (b) medical practitioner;
 - (c) private hospital;
 - (d) specialist.

In this instrument:

accredited prescriber of medication for the treatment of hepatitis B means a medical practitioner, or an authorised nurse practitioner, approved by a State or Territory to prescribe medication for the treatment of hepatitis B in accordance with this instrument.

accredited prescriber of medication for the treatment of hepatitis C means a medical practitioner, or an authorised nurse practitioner, approved by a State or Territory to prescribe medication for the treatment of hepatitis C in accordance with this instrument.

accredited prescriber of medication for the treatment of HIV or AIDS means a medical practitioner, or an authorised nurse practitioner, approved by a State or Territory to prescribe medication for the treatment of HIV or AIDS in accordance with this instrument.

accredited prescriber of medication for the treatment of schizophrenia means a medical practitioner approved by a State or Territory to prescribe medication for the treatment of schizophrenia in accordance with this instrument.

Act means the *National Health Act 1953*.

affiliated: a specialist is ***affiliated*** with a hospital if the specialist is:

- (a) a staff specialist of the hospital; or
- (b) a visiting or consulting specialist of the hospital.

approved ex-manufacturer price of a listed brand of a pharmaceutical item has the same meaning as in Part VII of the Act.

approved hospital authority has the same meaning as in Part VII of the Act, as affected by section 11 of this instrument.

approved medical practitioner has the same meaning as in Part VII of the Act.

approved pharmacist has the same meaning as in Part VII of the Act.

Approved Pharmacists Commonwealth Price Determination means the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020*.

Approved Pharmacists Conditions Determination means the *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017*.

approved supplier has the same meaning as in Part VII of the Act, as affected by section 11 of this instrument.

authorised nurse practitioner has the same meaning as in Part VII of the Act.

authorised prescriber has the meaning given by section 7.

CAR drug (short for Complex Authority Required drug) means any of the following highly specialised drugs:

- (a) abatacept;
- (b) adalimumab;
- (c) ambrisentan;
- (d) anifrolumab;
- (e) avatrombopag;
- (f) azacitidine;
- (g) benralizumab;
- (h) bosentan;
- (i) burosumab;
- (j) daunorubicin with cytarabine;
- (k) difelikefalin;
- (l) dupilumab;
- (m) eculizumab;
- (n) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
- (o) eltrombopag;
- (p) epoprostenol;
- (q) etanercept;
- (r) iloprost;
- (s) infliximab;
- (t) ivacaftor;
- (u) lenalidomide;
- (v) lumacaftor with ivacaftor;
- (w) macitentan;
- (x) mepolizumab;
- (y) midostaurin;
- (z) nusinersen;
- (aa) omalizumab;
- (bb) onasemnogene abeparvovec;
- (cc) pasireotide;
- (dd) pegcetacoplan;
- (ee) pegvisomant;
- (ff) pomalidomide;
- (gg) ravulizumab;
- (hh) riociguat;

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- (ii) risdiplam;
- (jj) romiplostim;
- (kk) selexipag;
- (ll) sildenafil;
- (mm) tadalafil;
- (nn) teduglutide;
- (oo) tezacaftor with ivacaftor and ivacaftor;
- (pp) tocilizumab;
- (qq) ustekinumab;
- (rr) vedolizumab.

circumstances code means the letter “C” followed by a number.

community access medication means any of the following:

- (a) medication for the treatment of hepatitis B;
- (b) medication for the treatment of HIV or AIDS, other than a pharmaceutical benefit that has the drug:
 - (i) azithromycin; or
 - (ii) doxorubicin - pegylated liposomal; or
 - (iii) rifabutin;
- (ba) medication for the treatment of opioid dependence;
- (c) medication for continuing treatment of schizophrenia;
- (d) lanreotide, if:
 - (i) the description of its form does not include “Powder for suspension for injection”; and
 - (ii) it is for continuing treatment;
- (e) octreotide, if:
 - (i) the description of its form includes “Injection (modified release)”; and
 - (ii) it is for continuing treatment.

CTG registered patient means a patient registered under subsection 10(2) of the CTG Special Arrangement.

CTG Special Arrangement means the *National Health (Closing the Gap – PBS Co-payment Program) Special Arrangement 2016*.

CTG supplier has the same meaning as in the CTG Special Arrangement.

dangerous drug has the same meaning as in the Approved Pharmacists Commonwealth Price Determination.

dangerous drug fee has the same meaning as in the Approved Pharmacists Commonwealth Price Determination.

day admitted patient: a person is a **day admitted patient** of a hospital on a day if, on that day, the person:

- (a) is admitted to the hospital (other than through the hospital's emergency department); and
 - (b) receives treatment; and
 - (c) is discharged from the hospital;
- in accordance with a pre-existing plan for the person's treatment.

dispensed price:

- (a) for a special arrangement supply of an HSD pharmaceutical benefit by an approved hospital authority for a public hospital—has the meaning given by section 29; and
- (b) for a special arrangement supply of an HSD pharmaceutical benefit by an approved supplier other than an approved hospital authority for a public hospital—has the meaning given by section 32.

EFC patient has the meaning given by subsection 8(7).

eligible patient has the meaning given by section 8.

General statement for drugs for the treatment of hepatitis C has the same meaning as in the Listing Instrument.

highly specialised drug means a listed drug mentioned in Schedule 1.

hospital authority has the same meaning as in Part VII of the Act.

HSD hospital authority means a hospital authority for which:

- (a) an approval under section 94 of the Act, as modified by section 10 of this instrument, is in force; or
- (b) an approval mentioned in section 38 of this instrument is in force.

HSD pharmaceutical benefit means a pharmaceutical benefit mentioned in Schedule 1.

listed drug has the same meaning as in Part VII of the Act.

Listing Instrument means the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024).

medication chart prescription has the same meaning as in the Regulations.

medication for the treatment of hepatitis B means any of the following:

- (a) adefovir;
- (b) entecavir;
- (c) lamivudine;
- (d) tenofovir.

medication for the treatment of hepatitis C means medication mentioned in the table in clause 3 of the General statement for drugs for the treatment of hepatitis C.

medication for the treatment of HIV or AIDS means any of the following:

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- (a) abacavir;
- (b) abacavir with lamivudine;
- (c) atazanavir;
- (d) atazanavir with cobicistat;
- (e) azithromycin;
- (f) bictegravir with emtricitabine with tenofovir alafenamide;
- (g) cabotegravir;
- (h) cabotegravir and rilpivirine;
- (i) darunavir;
- (j) darunavir with cobicistat;
- (k) darunavir with cobicistat, emtricitabine and tenofovir alafenamide;
- (l) dolutegravir;
- (m) dolutegravir with abacavir and lamivudine;
- (n) dolutegravir with lamivudine;
- (o) dolutegravir with rilpivirine;
- (p) doxorubicin - pegylated liposomal;
- (q) emtricitabine with rilpivirine with tenofovir alafenamide;
- (r) emtricitabine with tenofovir alafenamide;
- (s) etravirine;
- (t) ganciclovir;
- (u) lamivudine;
- (v) lamivudine with zidovudine;
- (w) lopinavir with ritonavir;
- (x) maraviroc;
- (y) nevirapine;
- (z) raltegravir;
- (aa) rifabutin;
- (bb) rilpivirine;
- (cc) ritonavir;
- (dd) tenofovir;
- (ee) tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat;
- (ff) tenofovir with emtricitabine;
- (gg) tenofovir with emtricitabine and efavirenz;
- (hh) valganciclovir;
- (ii) zidovudine.

medication for the treatment of opioid dependence means any of the following:

- (a) buprenorphine;
- (b) buprenorphine with naloxone;
- (c) methadone.

medication for the treatment of schizophrenia means clozapine.

ODT pharmaceutical benefit means an HSD pharmaceutical benefit that has a drug that is a medication for the treatment of opioid dependence.

pack quantity has the same meaning as in Part VII of the Act.

pharmaceutical benefit has the same meaning as in Part VII of the Act.

pharmaceutical item has the same meaning as in Part VII of the Act.

proportional ex-manufacturer price of a listed brand of a pharmaceutical item has the same meaning as in Part VII of the Act.

purposes code means the letter “P” followed by a number.

Regulations means the *National Health (Pharmaceutical Benefit) Regulations 2017*.

residential care service has the same meaning as in the Regulations.

special arrangement supply has the meaning given by sections 13 and 41.

UNAR drug (short for Unrestricted—No Authority Required drug) means any of the following highly specialised drugs:

- (a) rituximab.

7 Definition of *authorised prescriber*

Specialists affiliated with hospitals

- (1) A specialist is an **authorised prescriber** for an HSD pharmaceutical benefit for a patient receiving treatment in, at or from a hospital if the specialist is affiliated with the hospital.

Medical practitioners—with the agreement of specialists

- (2) A medical practitioner is an **authorised prescriber** for an HSD pharmaceutical benefit for a patient receiving treatment in, at or from a hospital if all of the following apply:
 - (a) the benefit is for continuing treatment for the patient;
 - (b) the patient’s treatment is being managed by a specialist;
 - (c) it is impractical for the patient to obtain a prescription for the benefit from the specialist;
 - (d) the specialist has agreed to the prescribing of the benefit for the patient by the medical practitioner.

Medical practitioners—if authorised by Commonwealth and State authorities

- (3) A medical practitioner is an **authorised prescriber** for an HSD pharmaceutical benefit for a patient if all of the following apply:
 - (a) the HSD pharmaceutical benefit is for continuing treatment for the patient;

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- (b) the medical practitioner is authorised (however described) by an authority of the Commonwealth for the purposes of this provision;
- (c) the medical practitioner is authorised (however described) by an authority of the State or Territory in which the hospital is located for the purposes of this provision.

Medical practitioners—medication for the treatment of hepatitis C, lanreotide and octreotide

- (4) A medical practitioner is an **authorised prescriber** for the following HSD pharmaceutical benefits:
 - (a) a benefit that has a drug that is a medication for the treatment of hepatitis C;
 - (b) a benefit that has the drug lanreotide, if:
 - (i) the description of its form does not include “Powder for suspension for injection”; and
 - (ii) it is for continuing treatment;
 - (c) a benefit that has the drug octreotide, if:
 - (i) the description of its form includes “Injection (modified release)”; and
 - (ii) it is for continuing treatment.

Accredited prescribers—HSD pharmaceutical benefits for the treatment of hepatitis B, hepatitis C, HIV or AIDS, and schizophrenia

- (5) The following table has effect.

Authorised prescribers for certain HSD pharmaceutical benefits

Item	Column 1 The following person ...	Column 2 is an <i>authorised prescriber</i> for an HSD pharmaceutical benefit that has a drug that is ...
1	An accredited prescriber of medication for the treatment of hepatitis B	a medication for the treatment of hepatitis B.
2	An accredited prescriber of medication for the treatment of hepatitis C	a medication for the treatment of hepatitis C.
3	An accredited prescriber of medication for the treatment of HIV or AIDS	a medication for the treatment of HIV or AIDS.
4	An accredited prescriber of medication for the treatment of schizophrenia	a medication for the treatment of schizophrenia.

Authorised nurse practitioners and medical practitioners—ODT pharmaceutical benefits

- (6) Each of the following is an **authorised prescriber** for an ODT pharmaceutical benefit:
 - (a) an authorised nurse practitioner;
 - (b) a medical practitioner.
-

- (7) To avoid doubt, a person is not an authorised prescriber, within the meaning of this instrument, for an HSD pharmaceutical benefit only because the person is authorised in accordance with section 12 of the Listing Instrument to write a prescription for the supply of the pharmaceutical benefit.

Note: A supply of an HSD pharmaceutical benefit is not a special arrangement supply of the benefit unless the supply was prescribed by an authorised prescriber for the benefit (see section 13 of this instrument).

8 Definition of *eligible patient*

Persons receiving treatment by medical practitioners at or from public hospitals other than as admitted patients

- (1) A person is an **eligible patient** for an HSD pharmaceutical benefit if the person:
- is, or is to be treated as, an eligible person; and
 - is receiving medical treatment by a medical practitioner at or from a public hospital; and
 - is receiving that treatment as:
 - a non-admitted patient of the hospital; or
 - a day admitted patient of the hospital; or
 - a patient on discharge from the hospital; and
 - is not an EFC patient (see subsection (7)) for the benefit.

Persons receiving treatment by authorised nurse practitioners at or from public hospitals other than as admitted patients—medication for the treatment of hepatitis C

- (2) A person is an **eligible patient** for an HSD pharmaceutical benefit that has a drug that is a medication for the treatment of hepatitis C if the person:
- is, or is to be treated as, an eligible person; and
 - is receiving medical treatment by an authorised nurse practitioner at or from a public hospital; and
 - is receiving that treatment as:
 - a non-admitted patient of the hospital; or
 - a day admitted patient of the hospital; or
 - a patient on discharge from the hospital.

Persons receiving treatment by medical practitioners in public hospitals as admitted patients—HSD pharmaceutical benefits that contain eculizumab for the treatment of atypical haemolytic uraemic syndrome

- (3) A person is an **eligible patient** for an HSD pharmaceutical benefit that has the drug eculizumab for the treatment of atypical haemolytic uraemic syndrome if the person:
- is, or is to be treated as, an eligible person; and
 - is receiving medical treatment by a medical practitioner in a public hospital; and

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- (c) is receiving that treatment as an admitted patient (other than a day admitted patient) of the hospital.

Persons receiving treatment by medical practitioners in, at or from private hospitals

- (4) A person is an **eligible patient** for an HSD pharmaceutical benefit if the person:
 - (a) is, or is to be treated as, an eligible person; and
 - (b) is receiving medical treatment by a medical practitioner in, at or from a private hospital; and
 - (c) is not an EFC patient (see subsection (7)) for the benefit.

Persons receiving treatment by authorised nurse practitioners in, at or from private hospitals—medication for the treatment of hepatitis C

- (5) A person is an **eligible patient** for an HSD pharmaceutical benefit that has a drug that is a medication for the treatment of hepatitis C if the person:
 - (a) is, or is to be treated as, an eligible person; and
 - (b) is receiving medical treatment by an authorised nurse practitioner in, at or from a private hospital.

Persons receiving HSD pharmaceutical benefits that have drugs that are community access medications

- (6) A person is an **eligible patient** for an HSD pharmaceutical benefit if:
 - (a) the benefit has a drug that is a community access medication; and
 - (b) the person is, or is to be treated as, an eligible person.

EFC patient

- (7) A person is an **EFC patient** for an HSD pharmaceutical benefit that has a UNAR drug if the benefit is or will be prescribed to the person:
 - (a) in accordance with the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*; or
 - (b) for the purposes of chemotherapy treatment for cancer.

Division 2—Supplies of HSD pharmaceutical benefits from hospitals

9 Supplies of HSD pharmaceutical benefits by approved hospital authorities to patients receiving treatment from hospitals

- (1) In this instrument, and in Part VII of the Act and regulations or other instruments made for the purposes of that Part, a reference to an approved hospital authority supplying pharmaceutical benefits to patients receiving treatment in or at the hospital of which it is the governing body or proprietor includes a reference to the hospital authority supplying HSD pharmaceutical benefits to patients receiving treatment from the hospital.
- (2) This section applies in addition to section 94 of the Act.

Division 3—HSD hospital authorities

10 HSD hospital authorities

- (1) Section 94 of the Act applies as if that section permitted the Minister to approve a hospital authority for the purpose of its supplying HSD pharmaceutical benefits to patients receiving treatment in, at or from the hospital of which it is the governing body or proprietor if the dispensing of those benefits is performed:
 - (a) other than at the hospital; and
 - (b) by or under the direct supervision of a medical practitioner or pharmacist.
- (2) Subsection (1) applies despite subsection 94(5) of the Act.

11 References to approved suppliers and approved hospital authorities

In this instrument, and in Part VII of the Act and regulations or other instruments made for the purposes of that Part, a reference to an approved supplier or an approved hospital authority includes a reference to an HSD hospital authority.

12 Numbers allotted to HSD hospital authorities

For the purposes of Part VII of the Act and regulations or other instruments made for the purposes of that Part, a number allotted to an HSD hospital authority under either of the following provisions is taken to have been allotted by the Minister under subsection 16(4) of the Regulations:

- (a) subsection 52(3) of the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010);
- (b) subsection 52(3) of the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010* (PB 63 of 2010).

Part 2—Special arrangement supplies of HSD pharmaceutical benefits

Division 1—Preliminary

13 Definition of *special arrangement supply*

Prescriptions written for public hospital patients

- (1) A supply of an HSD pharmaceutical benefit to a person is a ***special arrangement supply*** of the benefit if:
- (a) the person is an eligible patient for the benefit; and
 - (b) the benefit is supplied by:
 - (i) for any benefit—an approved hospital authority for a public hospital; or
 - (ii) for a benefit that has a CAR drug or UNAR drug—an approved pharmacist; and
 - (c) the benefit is supplied on the basis of a prescription written:
 - (i) when the person was receiving medical treatment in, at or from a public hospital; and
 - (ii) by an authorised prescriber for the benefit; and
 - (iii) unless the benefit has a UNAR drug—in circumstances mentioned in Schedule 3 for a circumstances code mentioned in the column headed “Circumstances” in Schedule 1 for the benefit.

Prescriptions written for private hospital patients

- (2) A supply of an HSD pharmaceutical benefit to a person is a ***special arrangement supply*** of the benefit if:
- (a) the person is an eligible patient for the benefit; and
 - (b) the benefit is supplied by:
 - (i) an approved hospital authority for a private hospital; or
 - (ii) an approved pharmacist; and
 - (c) the benefit is supplied on the basis of a prescription written:
 - (i) when the person was receiving medical treatment in, at or from a private hospital; and
 - (ii) by an authorised prescriber for the benefit; and
 - (iii) unless the benefit has a UNAR drug—in circumstances mentioned in Schedule 3 for a circumstances code mentioned in the column headed “Circumstances” in Schedule 1 for the benefit.

Community access arrangements

- (3) A supply of an HSD pharmaceutical benefit to a person is a ***special arrangement supply*** of the benefit if:
-

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- (a) the benefit has a drug that is a community access medication; and
- (b) the person is an eligible patient for the benefit; and
- (c) the benefit is supplied by an approved supplier; and
- (d) the benefit is supplied on the basis of a prescription written:
 - (i) by an authorised prescriber for the benefit; and
 - (ii) in circumstances mentioned in Schedule 3 for a circumstances code mentioned in the column headed “Circumstances” in Schedule 1 for the benefit.

Division 2—Prescribing of HSD pharmaceutical benefits

15 Prescription circumstances—general (Act s 85(7)(a) and (b))

- (1) For the purposes of paragraph 85(7)(a) of the Act, an HSD pharmaceutical benefit, other than a benefit that has a UNAR drug, is a relevant pharmaceutical benefit for the purposes of section 88A of the Act.
- (2) For the purposes of paragraph 85(7)(b) of the Act, the circumstances in which a prescription for a special arrangement supply of an HSD pharmaceutical benefit, other than a benefit that has a UNAR drug, may be written are the circumstances mentioned in Schedule 3 to this instrument for a circumstances code mentioned in the column headed “Circumstances” in Schedule 1 to this instrument for the benefit.
- (3) This section applies in addition to section 13 of the Listing Instrument.

16 Prescription circumstances—authority required procedures

- (1) This section applies to a prescription for a special arrangement supply of an HSD pharmaceutical benefit if the circumstances mentioned in Schedule 3 (if any) in which the prescription is written include:
 - (a) Compliance with Authority Required procedures; or
 - (b) Compliance with Written Authority Required procedures.
- (2) Section 19 of the Listing Instrument applies to the prescription as if:
 - (a) a reference to Part 1 of Schedule 4 to that instrument were a reference to Schedule 3 to this instrument; and
 - (b) a reference to an authorised prescriber were a reference to an authorised prescriber within the meaning of this instrument.

18 When medication chart prescriptions not to be written

HSD pharmaceutical benefits that have CAR drugs or rituximab

- (1) Subparagraph 39(a)(ii) of the Regulations does not apply to a prescription for a special arrangement supply of an HSD pharmaceutical benefit that has a CAR drug or rituximab.

Persons receiving treatment in residential care services

- (2) Subparagraph 41(1)(a)(i) of the Regulations does not apply to a prescription for a special arrangement supply of an HSD pharmaceutical benefit.

19 Prescriptions not to direct repeated supplies for visitors to Australia

- (1) An authorised prescriber for an HSD pharmaceutical benefit must not write a prescription directing a repeated supply of an HSD pharmaceutical benefit to a person who is a visitor to Australia even if the person is, in accordance with

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section 7 of the *Health Insurance Act 1973*, to be treated as an eligible person within the meaning of that Act.

- (2) This section applies despite section 85A of the Act.

20 Maximum quantity or number of units (Act s 85A(2)(a))

- (1) For the purposes of paragraph 85A(2)(a) of the Act, this section sets out the maximum quantity or number of units of the pharmaceutical item in an HSD pharmaceutical benefit that may, in one prescription for a special arrangement supply of the benefit, be directed by an authorised prescriber to be supplied on any one occasion.

Supply for particular purposes

- (2) If:
- (a) a purposes code is mentioned in the column headed “Purposes” in Schedule 1 to this instrument for the benefit; and
 - (b) the supply of the benefit is for purposes mentioned in Schedule 3 to this instrument for the purposes code;
- the maximum quantity or number of units is the quantity or number of units is mentioned in the column headed “Maximum quantity” in Schedule 1 to this instrument for the benefit and the purposes code.

Supply for all purposes—HSD pharmaceutical benefits not in Schedule 2

- (3) If:
- (a) a purposes code is not mentioned in the column headed “Purposes” in Schedule 1 to this instrument for the benefit; and
 - (b) a quantity or number of units is mentioned in the column headed “Maximum quantity” in Schedule 1 to this instrument for the benefit;
- the maximum quantity or number of units is that quantity or number of units.

Supply for all purposes—HSD pharmaceutical benefits in Schedule 2

- (4) If:
- (a) a purposes code is not mentioned in the column headed “Purposes” in Schedule 1 to this instrument for the benefit; and
 - (b) the words “See Schedule 2” appear in the column headed “Maximum quantity” in Schedule 1 to this instrument for the benefit; and
 - (c) the prescription is written in circumstances mentioned in Schedule 3 for a circumstances code mentioned in the column headed “Circumstances” in Schedule 2 to this instrument for the benefit;
- the maximum quantity or number of units is the quantity or number of units that is applicable under Schedule 2 to this instrument for the benefit and the circumstances code.

Application of this section

- (5) To the extent that this section provides for a matter not provided for in the Listing Instrument, this section applies in addition to the Listing Instrument.
- (6) To the extent that this section makes a different provision for a matter provided for in the Listing Instrument, this section applies despite the Listing Instrument.

21 Maximum number of repeats (Act s 85A(2)(b))

- (1) For the purposes of paragraph 85A(2)(b) of the Act, this section sets out the maximum number of occasions an authorised prescriber may, in one prescription, direct that a special arrangement supply of an HSD pharmaceutical benefit be repeated.

Supply for particular purposes

- (2) If:
 - (a) a purposes code is mentioned in the column headed “Purposes” in Schedule 1 to this instrument for the benefit; and
 - (b) the supply is for purposes mentioned in Schedule 3 to this instrument for the purposes code;

the maximum number is the number mentioned in the column headed “Maximum repeats” in Schedule 1 to this instrument for the benefit and the purposes code.

Supply for all purposes—HSD pharmaceutical benefits not in Schedule 2

- (3) If:
 - (a) a purposes code is not mentioned in the column headed “Purposes” in Schedule 1 to this instrument for the benefit; and
 - (b) a number is mentioned in the column headed “Maximum repeats” in Schedule 1 to this instrument for the benefit;

the maximum number is that number.

Supply for all purposes—HSD pharmaceutical benefits in Schedule 2

- (4) If:
 - (a) a purposes code is not mentioned in the column headed “Purposes” in Schedule 1 to this instrument for the benefit; and
 - (b) the words “See Schedule 2” appear in the column headed “Maximum repeats” in Schedule 1 for the benefit; and
 - (c) the prescription is written in circumstances mentioned in Schedule 3 for a circumstances code mentioned in the column headed “Circumstances” in Schedule 2 to this instrument for the benefit;

the maximum number is the number that is applicable under Schedule 2 to this instrument for the benefit and the circumstances code.

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Application of this section

- (5) To the extent that this section provides for a matter not provided for in the Listing Instrument, this section applies in addition to the Listing Instrument.
- (6) To the extent that this section makes a different provision for a matter provided for in the Listing Instrument, this section applies despite the Listing Instrument.

22 No variation of application of determination of maximum number of repeats or maximum number or quantity of units—HSD pharmaceutical benefits that have CAR drugs

Section 30 of the Regulations does not apply in relation to a practitioner (within the meaning of section 29 of the Regulations) who has written a prescription for a special arrangement supply of an HSD pharmaceutical benefit that has a CAR drug.

Note: Section 30 of the Regulations allows the Minister to vary the application of a determination under paragraph 85A(2)(a) or (b) of the Act in certain circumstances.

23 Records to be kept—prescriptions for HSD pharmaceutical benefits that have eculizumab for the treatment of atypical haemolytic uraemic syndrome

- (1) If an authorised prescriber for an HSD pharmaceutical benefit that has the drug eculizumab for the treatment of atypical haemolytic uraemic syndrome writes a prescription for a special arrangement supply of the benefit, a copy of any clinical records relating to the prescription, including records required to demonstrate that the prescription was written in compliance with the circumstances and purposes determined in relation to the benefit under subsection 85(7) of the Act, must be kept by:
 - (a) the approved hospital authority for the hospital in, at or from which the eligible patient is receiving treatment; or
 - (b) if the approved hospital authority is not able to keep the records—the authorised prescriber.
- (2) The records must be kept for 2 years after the date the prescription to which the records relate is written.

Division 3—Supplying HSD pharmaceutical benefits

24 Special patient contribution for certain HSD pharmaceutical benefits

- (1) This section applies to a special arrangement supply of an HSD pharmaceutical benefit mentioned in the following table.

Special patient contribution for certain HSD pharmaceutical benefits						
Item	Drug	Form	Manner of administration	Brand	Pack quantity	Claimed price (\$)
1	Lamivudine	Tablet 100 mg	Oral	Zeffix	28	28.09
2	Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valtrex	100	42.70

- (2) The *special patient contribution* for a pack quantity of a listed brand of a pharmaceutical item mentioned in the table is the amount that is the difference between:
- (a) the price that would have been the dispensed price for that quantity of the brand of the pharmaceutical item if that dispensed price had been based on the claimed price (within the meaning of Part VII of the Act) mentioned in the table for that quantity; and
 - (b) the dispensed price for that quantity of the brand of the pharmaceutical item.
- (3) This section applies despite subsection 85B(5) of the Act.

25 Conditions for approved pharmacists

Special arrangement supplies of certain HSD pharmaceutical benefits

- (1) The Approved Pharmacists Conditions Determination does not apply to the dispensing or supply of an HSD pharmaceutical benefit if:
- (a) the manner of administration of the benefit is injection or extracorporeal circulation; and
 - (b) the benefit does not have a drug that is a community access medication; and
 - (c) the supply is a special arrangement supply of the benefit.

ODT pharmaceutical benefits—special arrangement supplies through agents

- (2) If a supply of an ODT pharmaceutical benefit is a special arrangement supply of the benefit mentioned in subsection 26(2) of this instrument, the Approved Pharmacists Conditions Determination applies to the dispensing and supply of the benefit as if paragraph 6(e), subsection 9(1), section 10, paragraphs 14(a) and (b) and section 15 of that Determination were omitted.

Section 26

ODT pharmaceutical benefits—special arrangement supplies other than through agents

- (3) If a supply of an ODT pharmaceutical benefit is a special arrangement supply of the benefit other than a special arrangement supply of the benefit mentioned in subsection 26(2) of this instrument, the Approved Pharmacists Conditions Determination applies to the dispensing and supply of the benefit as if paragraph (c) of the definition of *dispensing step* in section 5 of that Determination were omitted.

26 Supplies need not be directly to persons

Supplies of HSD pharmaceutical benefits by HSD hospital authorities

- (1) An HSD hospital authority may make a special arrangement supply of an HSD pharmaceutical benefit to a person:
- (a) other than directly to the person; or
 - (b) through an agent.

Supplies of ODT pharmaceutical benefits by approved pharmacists and approved hospital authorities

- (2) An approved pharmacist or an approved hospital authority may make a special arrangement supply of an ODT pharmaceutical benefit to a person through a person or organisation:
- (a) that has premises in a State or Territory; and
 - (b) that is authorised (however described) by an authority of the State or Territory for the purposes of supplying medication for the treatment of opioid dependence.

Application of this section

- (3) This section applies in addition to section 94 of the Act.

27 Repeated supplies of pharmaceutical benefits

Section 51 of the Regulations does not apply to a special arrangement supply of HSD pharmaceutical benefits.

Part 3—Payment for special arrangement supplies of HSD pharmaceutical benefits

Division 1—Supplies by approved hospital authorities for public hospitals

28 Rates of payment for approved hospital authorities for public hospitals (Act s 99(4))

- (1) For the purposes of subsection 99(4) of the Act, the amount payable to an approved hospital authority for a public hospital in respect of a special arrangement supply of an HSD pharmaceutical benefit by the authority is the amount, if any, by which the dispensed price for the supply of the benefit exceeds the amount that the hospital authority was entitled to charge under section 87 of the Act in respect of the supply.

Note 1: Section 87 of the Act limits the amounts that approved hospital authorities can charge patients for the supply of pharmaceutical benefits.

Note 2: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

- (2) This section applies despite the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017* (PB 25 of 2017).

Note: See subsection 99(4) of the Act (read with section 9 of this instrument) for the entitlement of an approved hospital authority to payment for the supply of pharmaceutical benefits to patients receiving treatment in, at or from a hospital in respect of which the authority is approved.

29 Dispensed price for approved hospital authorities for public hospitals

- (1) The **dispensed price** for a special arrangement supply of an HSD pharmaceutical benefit by an approved hospital authority for a public hospital is as follows:
- (a) if the quantity of the benefit supplied is equal to a multiple of a pack quantity of the benefit—the sum of the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for each pack quantity;
 - (b) if the quantity of the benefit supplied is less than a pack quantity of the benefit (a **broken quantity**)—the amount worked out in accordance with subsection (2);
 - (c) if neither paragraph (a) or (b) applies to the quantity of the benefit supplied—the sum of:
 - (i) the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for each pack quantity; and
 - (ii) the amount calculated in accordance with subsection (2) for the remainder of the quantity that is a broken quantity.

Section 29

Broken quantities

- (2) For the purposes of paragraph (1)(b) and subparagraph (1)(c)(ii), the amount for a broken quantity is worked out by:
- (a) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and
 - (b) applying that percentage to the approved ex-manufacturer price or proportional ex-manufacturer price (as applicable) for the pack quantity.

Rounding

- (3) The dispensed price under subsection (1) is rounded to the nearest cent (rounding 0.5 cents upwards).

Division 2—Supplies by other approved suppliers

30 Entitlement to, and amount of, payment for approved pharmacists and approved medical practitioners

- (1) This section applies if:
- (a) an approved pharmacist or approved medical practitioner has supplied an HSD pharmaceutical benefit; and
 - (b) the supply is a special arrangement supply of the benefit.

Note: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

- (2) The approved pharmacist or approved medical practitioner is, subject to section 99AAA of the Act and the conditions determined under section 98C of the Act that are applicable at the time of the supply, entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of the benefit exceeds the amount that the approved pharmacist or approved medical practitioner was entitled to charge under section 87 of the Act in respect of the supply.

Note: Section 87 of the Act limits the amounts that approved pharmacists and approved medical practitioners can charge patients for the supply of pharmaceutical benefits.

- (3) This section applies despite subsections 99(2) and (2AA) of the Act.

30A Paragraph 99(3)(b) of the Act does not apply to certain HSD pharmaceutical benefits

Paragraph 99(3)(b) of the Act does not apply to a special arrangement supply of an HSD pharmaceutical benefit if:

- (a) the manner of administration of the benefit is injection or extracorporeal circulation; and
- (b) the benefit is not a community access medication.

31 Rates of payment for approved hospital authorities for private hospitals (Act s 99(4))

- (1) For the purposes of subsection 99(4) of the Act, the amount payable to an approved hospital authority for a private hospital in respect of a special arrangement supply of an HSD pharmaceutical benefit by the authority is the amount, if any, by which the dispensed price for the supply of the benefit exceeds the amount that the authority was entitled to charge under section 87 of the Act in respect of the supply.

Note 1: Section 87 of the Act limits the amounts that approved hospital authorities can charge patients for the supply of pharmaceutical benefits.

Note 2: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

Section 32

- (2) This section applies despite the *National Health (Commonwealth Price - Pharmaceutical benefits supplied by private hospitals) Determination 2020* (PB 99 of 2020).

Note: See subsection 99(4) of the Act (read with section 9 of this instrument) for the entitlement of an approved hospital authority to payment for the supply of pharmaceutical benefits to patients receiving treatment in, at or from a hospital in respect of which the authority is approved.

32 Dispensed price for approved suppliers other than approved hospital authorities for public hospitals

- (1) The **dispensed price** for a special arrangement supply of an HSD pharmaceutical benefit by an approved supplier other than an approved hospital authority for a public hospital is as follows:
- (a) if the quantity of the benefit supplied is equal to a multiple of a pack quantity of the benefit—the sum of:
 - (i) the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for each pack quantity; and
 - (ii) if the benefit is a ready-prepared pharmaceutical benefit—the mark-up mentioned in section 33 for each pack quantity, rounded to the nearest cent (rounding 0.5 cents upwards); and
 - (iii) the dispensing fee for the benefit in accordance with section 34; and
 - (iv) if the benefit is a ready-prepared pharmaceutical benefit and a dangerous drug—the dangerous drug fee;
 - (b) if the quantity of the benefit supplied is less than a pack quantity of the benefit (a **broken quantity**)—the sum of:
 - (i) the amount worked out in accordance with subsection (2); and
 - (ii) the dispensing fee for the benefit in accordance with section 34; and
 - (iii) if the benefit is a ready-prepared pharmaceutical benefit and a dangerous drug—the dangerous drug fee;
 - (c) if the quantity of the benefit supplied is more than a multiple of a pack quantity of the benefit—the sum of:
 - (i) the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for each pack quantity; and
 - (ii) if the benefit is a ready-prepared pharmaceutical benefit—the mark-up mentioned in section 33 for each pack quantity, rounded to the nearest cent (rounding 0.5 cents upwards); and
 - (iii) the amount worked out in accordance with subsection (2) for the remainder of the quantity that is a broken quantity; and
 - (iv) the dispensing fee for the benefit in accordance with section 34; and
 - (v) if the benefit is a ready-prepared pharmaceutical benefit and a dangerous drug—the dangerous drug fee.

Broken quantities

- (2) For the purposes of subparagraphs (1)(b)(i) and (c)(iii), the amount for a broken quantity is worked out by:

- (a) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and
- (b) applying that percentage to the sum of:
 - (i) the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for the pack quantity; and
 - (ii) if the benefit is a ready-prepared pharmaceutical benefit—the mark-up mentioned in section 33 for the pack quantity, rounded to the nearest cent (rounding 0.5 cents upwards).

Rounding

- (3) The dispensed price under subsection (1) is rounded to the nearest cent (rounding 0.5 cents upwards).

33 Mark-up for ready-prepared pharmaceutical benefits

For the purposes of subparagraphs 32(1)(a)(ii), (c)(ii) and (2)(b)(ii), the mark-up for a pack quantity of an HSD pharmaceutical benefit that is a ready-prepared pharmaceutical benefit is:

- (a) if the pack quantity of the benefit is equal to the maximum quantity of the benefit mentioned in section 20—the amount mentioned in the following table for the approved ex-manufacturer price (*AEMP*) or proportional ex-manufacturer price (*PEMP*) (as applicable) for that quantity; or
- (b) if the pack quantity of the benefit is less than the maximum quantity of the benefit mentioned in section 20:
 - (i) if the mark-up mentioned in the following table for the maximum quantity is a monetary amount—that monetary amount reduced proportionately for the relative quantities; or
 - (ii) if the mark-up mentioned in the following table for the maximum quantity is a percentage of the AEMP or PEMP (as applicable)—that percentage of the AEMP or PEMP for the pack quantity.

Mark-up for ready-prepared pharmaceutical benefits

Item	If the AEMP or PEMP (as applicable) for the maximum quantity is ...	the mark-up for the maximum quantity is ...
1	less than \$40	10% of the AEMP or PEMP
2	at least \$40 but not more than \$100	\$4
3	more than \$100 but not more than \$1,000	4% of the AEMP or PEMP
4	more than \$1,000	\$40

34 Dispensing fee

- (1) For the purposes of subparagraphs 32(1)(a)(iii), (b)(ii) and (c)(iv):
 - (a) the dispensing fee for the supply of an HSD pharmaceutical benefit is:
 - (i) if the benefit has a drug mentioned in subsection (2) in the form mentioned in that subsection for the drug—the

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- extemporaneously-prepared dispensing fee (within the meaning of the Approved Pharmacists Commonwealth Price Determination); or
- (ii) if subparagraph (i) does not apply—the ready-prepared dispensing fee (within the meaning of that Determination); and
- (b) if the authorised prescriber who prescribed the benefit, instead of directing a repeated supply of the benefit, directed the supply on one occasion of a quantity or number of units of the benefit, not exceeding the total quantity or number of units that could be prescribed if the authorised prescriber directed a repeated supply, the dispensed price for the supply of the benefit includes:
- (i) only one dispensing fee; and
 - (ii) only one dangerous drug fee.

Note: See section 49 of the Regulations for the circumstances in which such a supply may be directed.

- (2) For the purpose of subparagraph (1)(a)(i), the drugs and the forms for the drugs are as follows:
- (a) mycophenolic acid as a powder for oral suspension containing mycophenolate mofetil 1g per 5 mL, 165mL;
 - (b) valganciclovir as a powder for oral solution 50mg (as hydrochloride) per mL, 100 mL.

Part 3A—Supply to CTG registered patients by CTG suppliers

34A Application of this Part

This Part applies to a special arrangement supply (the *relevant supply*) of an HSD pharmaceutical benefit under this Special Arrangement if the relevant supply is made:

- (a) to an eligible patient who is a CTG registered patient; and
- (b) by an approved supplier who is a CTG supplier.

34B Application of the CTG Special Arrangement—co-payment and payment etc.

- (1) Despite sections 28, 30, 31 and 37 of this Special Arrangement, subsections 11(1), (2), (3), (3E) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the relevant supply under this Special Arrangement with the modification set out in subsection (2) of this section.
- (2) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this Special Arrangement.
- (3) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement to not apply in relation to the relevant supply under this Special Arrangement.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this Special Arrangement are instead dealt with under Part 4 of this Special Arrangement.

Part 4—Claims for payment for special arrangement supplies of HSD pharmaceutical benefits

35 Rules for providing information about supplies—definition of *under co-payment data*

The *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* apply to a special arrangement supply of an HSD pharmaceutical benefit by an approved supplier as if the definition of *under co-payment data* in that instrument were replaced with the following definition:

under co-payment data means information relating to a special arrangement supply of an HSD pharmaceutical benefit by an approved supplier where the amount payable by the Commonwealth is nil because the dispensed price for the supply of the benefit does not exceed the amount that the supplier was entitled to charge under section 87 of the Act in respect of the supply.

35A Claim for payment if an eligible patient is a CTG registered patient

If:

- (a) a claim for payment for a special arrangement supply of an HSD pharmaceutical benefit made under the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022* is made using the manual system referred to in section 99AAA of the Act; and
- (b) the claim is made:
 - (i) by an approved supplier who is a CTG supplier; and
 - (ii) in relation to a special arrangement supply of an HSD pharmaceutical benefit to an eligible patient who is a CTG registered patient;

the claim must include an indicator that the eligible patient is a CTG registered patient.

Part 5—Miscellaneous

36 Compliance and audit arrangements

- (1) If an approved supplier makes a special arrangement supply of an HSD pharmaceutical benefit, the approved supplier must keep adequate, secure and auditable records of all supplied HSD pharmaceutical benefits for which a claim is made.
- (2) The records must be kept in systems that are able to be audited by the Chief Executive Medicare on reasonable notice being given to the approved supplier.

37 *Value for safety net purposes for supplies*

Supplies by approved hospital authorities

- (1) The **value for safety net purposes** for a special arrangement supply of an HSD pharmaceutical benefit to a person by an approved hospital authority is the amount paid by the person for the supply of the benefit that is equivalent to the amount chargeable under subsection 87(5) of the Act for the supply of the benefit less the amount chargeable under that subsection because of subsection 87(2A) of the Act.

Note: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

Supplies by approved pharmacists and approved medical practitioners

- (2) The **value for safety net purposes** for a special arrangement supply of an HSD pharmaceutical benefit to a person by an approved pharmacist or approved medical practitioner is the amount paid by the person for the supply of the benefit that is equivalent to the amount chargeable under section 87 of the Act for the supply of the benefit less the amount chargeable under subsection 87(2A) of the Act.

Note: However, see Part 3A in relation to a special arrangement supply of an HSD pharmaceutical benefit to a CTG registered patient by a CTG supplier.

Application of this section

- (3) This section applies despite regulation 17A of the Regulations.

Part 6—Application, saving and transitional provisions

Division 1—Provisions relating to this instrument as made

38 HSD hospital authorities

Despite the repeal of the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010):

- (a) an approval that was in force under subsection 52(2) of that instrument immediately before 1 April 2021; and
- (b) an approval that was continued in force under section 53 of that instrument as if it were an approval under subsection 52(2) of that instrument, and was in force immediately before 1 April 2021;

continues in force as if it were an approval under section 94 of the Act, as modified by section 10 of this instrument.

Division 2—Provisions relating to the National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023

39 Purpose of this Division

This Division makes provision in relation to certain pre-commencement prescriptions for the purpose of the application of Part VII of the Act, and regulations and other instruments made for the purposes of that Part, to those prescriptions.

40 Definitions

In this Division:

Claims Rules means the *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022*.

pre-commencement benefit: see section 50.

pre-commencement prescription: a prescription is a **pre-commencement prescription** if:

- (a) the prescription was written:
 - (i) before 1 July 2023; and
 - (ii) by an authorised nurse practitioner or a medical practitioner; and
 - (iii) for the supply to a person of a drug that is a medication for the treatment of opioid dependence; and
 - (iv) in the circumstance that the prescription was for the treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal; and
- (b) immediately before 1 July 2023, a pre-commencement benefit could have been supplied to the person on the basis of the prescription.

41 Definition of special arrangement supply

A supply of an ODT pharmaceutical benefit is a **special arrangement supply** of the benefit if the benefit is supplied:

- (a) on or after 1 July 2023; and
- (b) to a person who is, or is to be treated as, an eligible person; and
- (c) by an approved supplier; and
- (d) on the basis of a pre-commencement prescription (as affected by this Division, if applicable); and
- (e) in accordance with this Division.

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42 Prescriptions directing supply for dispensing over time

- (1) This section applies if a pre-commencement prescription directed the supply of a specified quantity or number of units (whether expressed as a total or as a dose) to be dispensed over a specified period of time (the *directed dispensing period*).

Deemed variation of application of determination of maximum number or quantity of units

- (2) If the specified quantity or number of units, or the quantity or number of units required for the doses over the directed dispensing period, is more than the maximum quantity or number of units mentioned in Schedule 1 for the pharmaceutical benefit to be supplied on the basis of the prescription:
- (a) the application of the determination of the maximum quantity or number of units under paragraph 85A(2)(a) of the Act for the benefit is taken to have been varied under section 30 of the Regulations; and
 - (b) the prescription is taken to have been authorised in accordance with subsection 30(4) of the Regulations; and
 - (c) the number P2023OD is taken to have been allotted to, and marked on, the prescription as mentioned in subsection 30(5) of the Regulations.

Deemed modification of prescription—remaining period of up to 28 days

- (3) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the period remaining in the directed dispensing period (the *remaining period*) is not more than 28 days, the prescription is taken to direct the supply on one occasion of the total quantity or number of units required for the remaining period.

Deemed modification of prescription—remaining period of 29 to 55 days

- (4) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the remaining period is more than 28 days but not more than 55 days, the prescription is taken to direct the supply on one occasion of the total quantity or number of units required for 28 days.

Deemed modification of prescription—remaining period of 56 to 83 days

- (5) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the remaining period is more than 55 days but not more than 83 days, the prescription is taken to direct:
- (a) the supply on any one occasion of the total quantity or number of units required for 28 days; and
 - (b) that the supply be repeated once.

Deemed modification of prescription—remaining period of 84 days or more

- (6) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the remaining period is 84 days or more, the prescription is taken to direct:
- (a) the supply on any one occasion of the total quantity or number of units required for 28 days; and
 - (b) that the supply be repeated twice.

43 Prescriptions directing supply of buprenorphine for injection

- (1) This section applies if:
- (a) a pre-commencement prescription is for the supply of the drug buprenorphine with the manner of administration injection (the **medication**); and
 - (b) the prescription directed the supply of a specified quantity or number of units of the medication (the **directed quantity**) that is more than the quantity of the medication mentioned in subsection (2) (the **standard quantity** for the medication).
- (2) For the purposes of paragraph (1)(b), the standard quantity for the medication is:
- (a) if the brand of the medication is Buvidal Weekly—4; or
 - (b) if the brand of the medication is Buvidal Monthly or Sublocade—1.

Deemed modification of prescription—remaining quantity of not more than standard quantity

- (3) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the quantity or number of units of the medication that remains to be supplied (the **remaining quantity**) is not more than the standard quantity for the medication, the prescription is taken to direct the supply on one occasion of the remaining quantity.

Deemed modification of prescription—remaining quantity of more than standard quantity but less than twice standard quantity

- (4) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the remaining quantity is more than the standard quantity for the medication but is less than twice the standard quantity for the medication, the prescription is taken to direct the supply on one occasion of the standard quantity for the medication.

Deemed modification of prescription—remaining quantity of more than twice standard quantity but less than 3 times standard quantity

- (5) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the remaining quantity is more than twice the standard quantity for the medication but is less than 3 times the standard quantity for the medication, the prescription is taken to direct:
-

Part 6 Application, saving and transitional provisions

Division 2 Provisions relating to the National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023

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- (a) the supply on any one occasion of the standard quantity for the medication; and
- (b) that the supply be repeated once.

Deemed modification of prescription—remaining quantity of 3 times standard quantity or more

- (6) If, when the prescription is first presented to an approved supplier on or after 1 July 2023, the remaining quantity is 3 times the standard quantity for the medication or more, the prescription is taken to direct:
 - (a) the supply on any one occasion of the standard quantity for the medication; and
 - (b) that the supply be repeated twice.

44 Prescriptions directing supply of methadone

- (1) This section applies if a pre-commencement prescription is for the supply of the drug methadone.
- (2) On the basis of the prescription, the person for whom the prescription was written is entitled to receive, and an approved supplier may supply to the person, any ODT pharmaceutical benefit that has the drug methadone.
- (3) This section applies despite section 89 and paragraph 103(2)(a) of the Act.

45 First supply on or after 1 July 2023 deemed to be supply on first presentation

If the first supply of an ODT pharmaceutical benefit by an approved supplier on the basis of a pre-commencement prescription on or after 1 July 2023 is not a supply of that benefit on first presentation of the prescription, it is taken to be a supply of that benefit on first presentation of the prescription.

46 Supply on first presentation of prescription (Regulations s 44)

Subparagraphs 44(2)(a)(i) and (3)(a)(i) of the Regulations do not apply to a special arrangement supply of an ODT pharmaceutical benefit on the basis of a pre-commencement prescription.

47 Repeat authorisations (Regulations s 52)

- (1) Section 52 of the Regulations applies to the supply of an ODT pharmaceutical benefit on the basis of a pre-commencement prescription to which subsection 42(5) or (6) or 43(5) or (6) of this instrument applies as if the benefit were supplied in the circumstances set out in subsection 52(2) of the Regulations.
- (2) Subsection 52(3) of the Regulations applies in relation to a pre-commencement prescription as if the prescription had been authorised in accordance with authority required procedures that are part of the circumstances determined by

the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit to be supplied on the basis of the prescription.

48 Prescriptions written in electronic form—additional procedures for giving information (Claims Rules s 7) and keeping documents

Additional procedures for giving information

- (1) Section 7 of the Claims Rules applies in relation to a pre-commencement prescription written in electronic form as if a reference in that section to the prescription were a reference to a print-out of the prescription.

Keeping print-outs of prescriptions

- (2) If an approved supplier supplies a pharmaceutical benefit on the basis of a pre-commencement prescription written in electronic form, the approved supplier must keep a print-out of the prescription for at least 2 years from the date the pharmaceutical benefit was supplied by the approved supplier.

49 Information to be given using Claims Transmission System (Claims Rules Sch 1)

General

- (1) The table in clause 1 of Schedule 1 to the Claims Rules applies to a pre-commencement prescription as follows:
 - (a) as if, for the purposes of item 2 of the table, the Authority Prescription Number for the prescription were 00000641;
 - (b) as if, for the purposes of item 8 of the table, the prescription were signed on 1 July 2023;
 - (c) if the authorised nurse practitioner or medical practitioner who wrote the prescription did not write their PBS prescriber number on the prescription—as if, for the purposes of item 28 of the table, that number were written on the prescription;
 - (d) if the authorised nurse practitioner or medical practitioner who wrote the prescription did not write their prescriber ID on the prescription—as if, for the purposes of item 31 of the table, that number were written on the prescription;
 - (e) if the prescription was written in electronic form—as if, for the purposes of item 32 of the table, the prescription were a paper-based prescription;
 - (f) as if, for the purposes of item 40 of the table, the authorised nurse practitioner or medical practitioner who wrote the prescription had written on the prescription:
 - (i) the words “Streamlined Authority Code”; and
 - (ii) the relevant streamlined authority code included in any circumstances mentioned in an item of the table in Part 1 of Schedule 4 to the Listing

Part 6 Application, saving and transitional provisions

Division 2 Provisions relating to the National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023

Section 50

Instrument for the writing of a prescription for a pharmaceutical benefit for the treatment of opioid dependence.

Pre-commencement prescriptions written in electronic form

- (2) Clause 2 of Schedule 1 to the Claims Rules does not apply to a pre-commencement prescription written in electronic form.

50 Pre-commencement benefits

Each pharmaceutical benefit specified in the following table is a *pre-commencement benefit*.

Pre-commencement benefits				
Item	Listed drug	Form	Manner of administration	Brand
1	Buprenorphine	Injection (modified release) 8 mg in 0.16 mL pre-filled syringe	Injection	Buvidal Weekly
2	Buprenorphine	Injection (modified release) 16 mg in 0.32 mL pre-filled syringe	Injection	Buvidal Weekly
3	Buprenorphine	Injection (modified release) 24 mg in 0.48 mL pre-filled syringe	Injection	Buvidal Weekly
4	Buprenorphine	Injection (modified release) 32 mg in 0.64 mL pre-filled syringe	Injection	Buvidal Weekly
5	Buprenorphine	Injection (modified release) 64 mg in 0.18 mL pre-filled syringe	Injection	Buvidal Monthly
6	Buprenorphine	Injection (modified release) 96 mg in 0.27 mL pre-filled syringe	Injection	Buvidal Monthly
7	Buprenorphine	Injection (modified release) 128 mg in 0.36 mL pre-filled syringe	Injection	Buvidal Monthly
8	Buprenorphine	Injection (modified release) 160 mg in 0.45 mL pre-filled syringe	Injection	Buvidal Monthly
9	Buprenorphine	Injection (modified release) 100 mg in 0.50 mL pre-filled syringe	Injection	Sublocade
10	Buprenorphine	Injection (modified release) 300 mg in 1.50 mL pre-filled syringe	Injection	Sublocade
11	Buprenorphine	Tablet (sublingual) 400 micrograms (as hydrochloride)	Sublingual	Subutex
12	Buprenorphine	Tablet (sublingual) 2 mg (as hydrochloride)	Sublingual	Subutex
13	Buprenorphine	Tablet (sublingual) 8 mg (as hydrochloride)	Sublingual	Subutex
14	Buprenorphine with naloxone	Film (soluble) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	Sublingual	Suboxone Film 2/0.5
15	Buprenorphine	Film (soluble) 8 mg (as	Sublingual	Suboxone

Section 50

Pre-commencement benefits				
Item	Listed drug	Form	Manner of administration	Brand
	with naloxone	hydrochloride)-2 mg (as hydrochloride)		Film 8/2
16	Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL	Oral	Bidone Forte
17	Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL	Oral	Aspen Methadone Syrup
18	Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L	Oral	Bidone Forte
19	Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L	Oral	Aspen Methadone Syrup

Note: The drugs mentioned in the table were declared by the Minister under subsection 85(2) of the Act, and the forms, manners of administration and brands mentioned in the table were determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively—see the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) as in force before 1 July 2023.

Schedule 1—HSD pharmaceutical benefits and related information

Note: See the definitions of *highly specialised drug* and *HSD pharmaceutical benefit* in section 6, and sections 13, 15, 20 and 21.

1 Highly specialised drugs and HSD pharmaceutical benefits

- (1) Each listed drug specified in the following table is a highly specialised drug.
- (2) Each pharmaceutical benefit specified in the following table is an HSD pharmaceutical benefit.
- (3) The following table also specifies circumstances, purposes, maximum quantities and maximum repeats for HSD pharmaceutical benefits.

Note: The drugs mentioned in the table have been declared by the Minister under subsection 85(2) of the Act. The forms, manners of administration and brands mentioned in the table have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

HSD pharmaceutical benefits and related information							
Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Abacavir	Oral solution 20 mg (as sulfate) per mL, 240 mL	Oral	Ziagen	C13920		8	5
	Tablet 300 mg (as sulfate)	Oral	Ziagen	C4454 C4512		120	5
Abacavir with Lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	ABACAVIR/LAMIVU	C4527 C4528		60	5
			DINE 600/300 SUN				
			Abacavir/ Lamivudine Mylan	C4527 C4528		60	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Abacavir/Lamivudine Viatrix	C4527 C4528		60	5
			Kivexa	C4527 C4528		60	5
Abatacept	Powder for I.V. infusion 250 mg	Injection	Orencia	C14488 C14507 C14519 C14523 C14524 C14555 C14604 C14617		See Schedule 2	See Schedule 2
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Humira	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Amgevita	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Adalicip	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Humira	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Yuflyma	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
	Injection 40 mg in 0.4 mL pre-filled syringe	Injection	Adalicip	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Humira	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2

Schedule 1 HSD pharmaceutical benefits and related information

Clause 1

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Yuflyma	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Amgevita	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Hadlima	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Hyrimoz	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Idacio	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Amgevita	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Hadlima	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Hyrimoz	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
			Idacio	C12120 C14061 C14063 C14064 C14107 C14136		See Schedule 2	See Schedule 2
Adefovir	Tablet containing adefovir dipivoxil 10 mg	Oral	APO-Adefovir	C4490 C4510		60	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet containing adefovir dipivoxil 10 mg (S19A)	Oral	Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories)	C4490 C4510		60	5
Alemtuzumab	Solution concentrate for I.V. infusion 12 mg in 1.2 mL	Injection	Lemtrada	C6847 C7714 C9589 C9636	P6847 P9589	3	0
				C6847 C7714 C9589 C9636	P7714 P9636	5	0
Ambrisentan	Tablet 5 mg	Oral	Ambrisentan Viatrix	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
			Cipla Ambrisentan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
			PULMORIS	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
			Volibris	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet 10 mg	Oral	Ambrisentan Viatrix	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
			Cipla Ambrisentan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
			PULMORIS	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
			Volibris	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2
Anakinra	Injection 100 mg in 0.67 mL single use pre-filled syringe	Injection	Kineret	C5450		28	5
Anifrolumab	Solution concentrate for I.V. infusion 300 mg in 2 mL	Injection	Saphnelo	C15387 C15388 C15426		See Schedule 2	See Schedule 2
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	Injection	Movapo	C11385 C11445		180	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	Apomine Solution for Infusion	C10830 C10863		90	5
	Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe	Injection	Movapo PFS	C11385 C11445		180	5
	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Apomine Intermittent	C10830 C10863		100	5
			Movapo Pen	C10830 C10863		100	5
Atazanavir	Capsule 200 mg (as sulfate)	Oral	Reyataz	C4454 C4512		120	5
	Capsule 300 mg (as sulfate)	Oral	Reyataz	C4454 C4512		60	5
Atazanavir with cobicistat	Tablet containing 300 mg atazanavir and 150 mg cobicistat	Oral	Evotaz	C4454 C4512		60	5
Avatrombopag	Tablet 20 mg	Oral	Doptelet	C14054 C14130 C15340 C15375		See Schedule 2	See Schedule 2

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HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Accord	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2
			Azacitidine Dr.Reddy's	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2
			AZACITIDINE EUGIA	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2
			Azacitidine Juno	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2
			Azacitidine MSN	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2
			Azacitidine Sandoz	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2
			Azacitidine-Teva	C12439 C12983 C12986 C13010 C13011 C13012 C13015 C13029		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Azithromycin	Tablet 600 mg (as dihydrate)	Oral	Zithromax	C6356 C9604		16	5
Baclofen	Intrathecal injection 10 mg in 5 mL	Injection	Bacethecal	C6911 C6925 C6939 C6940 C9488 C9489 C9524 C9637		10	0
			Lioresal Intrathecal	C6911 C6925 C6939 C6940 C9488 C9489 C9524 C9637		10	0
			Sintetica Baclofen Intrathecal	C6911 C6925 C6939 C6940 C9488 C9489 C9524 C9637		10	0
	Intrathecal injection 40 mg in 20 mL	Injection	Sintetica Baclofen Intrathecal	C7134 C7148 C7152 C7153 C9525 C9562 C9606 C9638		2	0
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection	Fasenra Pen	C15353 C15376 C15383 C15444		See Schedule 2	See Schedule 2
Bictegravir with emtricitabine with tenofovir alafenamide	Tablet containing bictegravir 50 mg with emtricitabine 200 mg with tenofovir alafenamide 25 mg	Oral	Biktarvy	C4470 C4522		60	5
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Bosentan APO	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2

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HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			BOSENTAN DR.REDDY'S	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			Bosentan Mylan	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			Bosentan RBX	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			BOSLEER	C11229 C12425 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
	Tablet 125 mg (as monohydrate)	Oral	Bosentan APO	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			Bosentan Cipla	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			BOSENTAN DR.REDDY'S	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Bosentan GH	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			Bosentan Mylan	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			Bosentan RBX	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
			BOSLEER	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632		See Schedule 2	See Schedule 2
Buprenorphine	Injection (modified release) 8 mg in 0.16 mL pre-filled syringe	Injection	Buvidal Weekly	C15385		4	5
	Injection (modified release) 16 mg in 0.32 mL pre-filled syringe	Injection	Buvidal Weekly	C15385		4	5
	Injection (modified release) 24 mg in 0.48 mL pre-filled syringe	Injection	Buvidal Weekly	C15385		4	5
	Injection (modified release) 32 mg in 0.64 mL pre-filled syringe	Injection	Buvidal Weekly	C15385		4	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection (modified release) 64 mg in 0.18 mL pre-filled syringe	Injection	Buvidal Monthly	C15356		1	5
	Injection (modified release) 96 mg in 0.27 mL pre-filled syringe	Injection	Buvidal Monthly	C15356		1	5
	Injection (modified release) 100 mg in 0.5 mL pre-filled syringe	Injection	Sublocade	C15439		1	5
	Injection (modified release) 128 mg in 0.36 mL pre-filled syringe	Injection	Buvidal Monthly	C15356		1	5
	Injection (modified release) 160 mg in 0.45 mL pre-filled syringe	Injection	Buvidal Monthly	C15356		1	5
	Injection (modified release) 300 mg in 1.5 mL pre-filled syringe	Injection	Sublocade	C15439		1	5
	Tablet (sublingual) 400 micrograms (as hydrochloride)	Sublingual	Subutex	C15355		28	5
	Tablet (sublingual) 2 mg (as hydrochloride)	Sublingual	Subutex	C15355		84	5
	Tablet (sublingual) 8 mg (as hydrochloride)	Sublingual	Subutex	C15355		112	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Buprenorphine with naloxone	Film (soluble) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	Sublingual	Suboxone Film 2/0.5	C15355		84	5
	Film (soluble) 8 mg (as hydrochloride)-2 mg (as hydrochloride)	Sublingual	Suboxone Film 8/2	C15355		112	5
Burosumab	Solution for injection 10 mg in 1 mL	Injection	Crysvita	C13330 C13377		See Schedule 2	See Schedule 2
	Solution for injection 20 mg in 1 mL	Injection	Crysvita	C13330 C13377		See Schedule 2	See Schedule 2
	Solution for injection 30 mg in 1 mL	Injection	Crysvita	C13330 C13377		See Schedule 2	See Schedule 2
Cabotegravir	Tablet 30 mg	Oral	Vocabria	C12619		30	0
Cabotegravir and rilpivirine	Pack containing 1 vial cabotegravir 600 mg in 3 mL and 1 vial rilpivirine 900 mg in 3 mL	Injection	Cabenuva	C12636		1	5
Ciclosporin	Capsule 10 mg	Oral	Neoral 10	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Capsule 25 mg	Oral	APO-Ciclosporin	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
			Cyclosporin Sandoz	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
			Neoral 25	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
	Capsule 50 mg	Oral	APO-Ciclosporin	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
			Cyclosporin Sandoz	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
			Neoral 50	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
	Capsule 100 mg	Oral	APO-Ciclosporin	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Cyclosporin Sandoz	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
			Neoral 100	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		120	5
	Oral liquid 100 mg per mL, 50 mL	Oral	Neoral	C6631 C6638 C6643 C6660 C9694 C9695 C9742 C9764 C15360 C15361		4	5
	Solution concentrate for I.V. infusion 50 mg in 1 mL	Injection	Sandimmun	C6628 C9831		10	0
Cinacalcet	Tablet 30 mg (as hydrochloride)	Oral	Cinacalcet Viatris	C10063 C10067 C10073		56	5
			Pharmacor Cinacalcet	C10063 C10067 C10073		56	5
	Tablet 60 mg (as hydrochloride)	Oral	Cinacalcet Viatris	C10063 C10067 C10073		56	5
			Pharmacor Cinacalcet	C10063 C10067 C10073		56	5
	Tablet 90 mg (as hydrochloride)	Oral	Cinacalcet Mylan	C10063 C10067 C10073		56	5
			Cinacalcet Viatris	C10063 C10067 C10073		56	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Pharmacor Cinacalcet	C10063 C10067 C10073		56	5
Clozapine	Oral liquid 50 mg per mL, 100 mL	Oral	Clopine Suspension	C4998 C5015 C9490		1	0
	Tablet 25 mg	Oral	Versacloz Clopine 25	C4998 C5015 C9490 C4998 C5015 C9490		1 200	0 0
	Tablet 50 mg	Oral	Clozaril 25 Clozitor Clopine 50	C4998 C5015 C9490 C4998 C5015 C9490 C4998 C5015 C9490		200 200 200	0 0 0
	Tablet 100 mg	Oral	Clozitor Clopine 100	C4998 C5015 C9490 C4998 C5015 C9490		200 200	0 0
	Tablet 200 mg	Oral	Clozaril 100 Clozitor Clopine 200	C4998 C5015 C9490 C4998 C5015 C9490 C4998 C5015 C9490		200 200 200	0 0 0
Darbepoetin alfa	Injection 10 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 20 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
	Injection 20 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 40 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
	Injection 40 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 50 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 60 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
	Injection 60 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 80 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
	Injection 80 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 100 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
	Injection 100 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 150 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
	Injection 150 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
Darunavir	Tablet 600 mg	Oral	Darunavir Juno	C5094		120	5
	Tablet 600 mg (as ethanolate)	Oral	Prezista	C5094		120	5
	Tablet 800 mg	Oral	Darunavir Juno	C4313		60	5
	Tablet 800mg (as ethanolate)	Oral	Prezista	C4313		60	5
Darunavir with cobicistat	Tablet containing darunavir 800mg with cobicistat 150 mg	Oral	Prezcobix	C6377 C6413 C6428		60	5
Darunavir with cobicistat, emtricitabine and tenofovir alafenamide	Tablet containing darunavir 800 mg with cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg	Oral	Symtuza	C10317 C10324		60	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Daunorubicin with cytarabine	Powder for I.V. infusion containing daunorubicin 44 mg (as hydrochloride) and cytarabine 100 mg	Injection	Vyxeos	C15390 C15413		See Schedule 2	See Schedule 2
Deferasirox	Tablet 90 mg	Oral	Deferasirox ARX	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Deferasirox Sandoz	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2

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HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			DEFERASIROX-TE VA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Eferas	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Pharmacor	C7374 C7375 C7385 C8326	P7385	180	2
			Deferasirox FC	C8328 C8329 C9222 C9258 C9302	P8326 P8328 P8329 P9222 P9258 P9302		
			Deferasirox ARX	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Deferasirox Sandoz	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			DEFERASIROX-TE VA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Eferas	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5

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HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Pharmacor Deferasirox FC	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
	Tablet 180 mg	Oral	Deferasirox ARX	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Deferasirox Sandoz	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			DEFERASIROX-TE VA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Eferas	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Pharmacor	C7374 C7375 C7385 C8326	P7385	180	2
			Deferasirox FC	C8328 C8329 C9222 C9258 C9302	P8326 P8328 P8329 P9222 P9258 P9302		
			Deferasirox ARX	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Deferasirox Sandoz	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			DEFERASIROX-TE VA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Eferas	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Pharmacor Deferasirox FC	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
	Tablet 360 mg	Oral	Deferasirox ARX	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Deferasirox Sandoz	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2

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HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			DEFERASIROX-TE VA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Eferas	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
			Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Pharmacor	C7374 C7375 C7385 C8326	P7385	180	2
			Deferasirox FC	C8328 C8329 C9222 C9258 C9302	P8326 P8328 P8329 P9222 P9258 P9302		
			Deferasirox ARX	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Deferasirox Sandoz	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			DEFERASIROX-TE VA	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Eferas	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
			Pharmacor Deferasirox FC	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
	Tablet, dispersible, 125 mg	Oral	Deferasirox Juno	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2
			Pharmacor Deferasirox	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Deferasirox Juno	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5
			Pharmacor Deferasirox	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5
	Tablet, dispersible, 250 mg	Oral	Deferasirox Juno	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2
			Pharmacor Deferasirox	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Deferasirox Juno	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5
			Pharmacor Deferasirox	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5
	Tablet, dispersible, 500 mg	Oral	Deferasirox Juno	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2
			Pharmacor Deferasirox	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	168	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Deferasirox Juno	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5
			Pharmacor Deferasirox	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	168	5
Deferiprone	Oral solution 100 mg per mL, 250 mL	Oral	Ferriprox	C6403 C6448 C9228 C9286		5	5
	Tablet 500 mg	Oral	Ferriprox	C6403 C6448 C9228 C9286		300	5
	Tablet 1000 mg	Oral	Ferriprox	C6403 C6448 C9590 C9623		300	5
Desferrioxamine	Powder for injection containing desferrioxamine mesilate 500 mg	Injection	DBL Desferrioxamine Mesilate	C6394 C9696		400	5
	Powder for injection containing desferrioxamine mesilate 2 g	Injection	DBL Desferrioxamine Mesilate	C6394 C9696		60	5
Difelikefalin	Solution for I.V. injection 50 micrograms (as acetate) in 1 mL	Injection	Korsuva	C15171 C15211 C15227		See Schedule 2	See Schedule 2
Dolutegravir	Tablet 50mg (as sodium)	Oral	Tivicay	C4454 C4512		60	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Dolutegravir with abacavir and lamivudine	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	Oral	Triumeq	C9981 C10116		60	5
Dolutegravir with lamivudine	Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg	Oral	Dovato	C9987 C11066		60	5
Dolutegravir with rilpivirine	Tablet containing dolutegravir 50 mg (as sodium) with rilpivirine 25 mg (as hydrochloride)	Oral	Juluca	C8214 C8226		60	5
Dornase Alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation	Pulmozyme	C5634 C5635 C5740 C9591 C9592 C9624		60	5
Doxorubicin - Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	C6234 C6274 C9223 C9287		4	5
			Liposomal Doxorubicin SUN	C6234 C6274 C9223 C9287		4	5
Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled syringe	Injection	Dupixent	C15341 C15348 C15433		See Schedule 2	See Schedule 2
	Injection 300 mg in 2 mL single dose pre-filled syringe	Injection	Dupixent	C15348 C15424 C15425		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Eculizumab	Solution concentrate for I.V. infusion 300 mg in 30 mL	Injection	Soliris	C13458 C13459 C13464 C13560 C13660 C13661 C13684 C13845 C13857 C14750 C14753 C14754 C14781 C14792 C14793 C14799 C14805		See Schedule 2	See Schedule 2
Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg	Oral	Trikafta	C13932 C13991		See Schedule 2	See Schedule 2
	Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg	Oral	Trikafta	C13962 C13980		See Schedule 2	See Schedule 2
Eltrombopag	Tablet 25 mg (as olamine)	Oral	Revolade	C13327 C14126 C14127 C14129 C15173 C15174 C15191 C15192		See Schedule 2	See Schedule 2
	Tablet 50 mg (as olamine)	Oral	Revolade	C13327 C14126 C14127 C14129 C15173 C15174 C15191 C15192		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Emtricitabine with rilpivirine with tenofovir alafenamide	Tablet containing emtricitabine 200 mg with rilpivirine 25 mg with tenofovir alafenamide 25 mg	Oral	Odefsey	C4470 C4522		60	5
Emtricitabine with tenofovir alafenamide	Tablet containing emtricitabine 200 mg with tenofovir alafenamide 10 mg	Oral	Descovy	C4454 C4512		60	5
	Tablet containing emtricitabine 200 mg with tenofovir alafenamide 25 mg	Oral	Descovy	C4454 C4512		60	5
Entecavir	Tablet 0.5 mg (as monohydrate)	Oral	ENTAC	C4993 C5036		60	5
			ENTECAVIR APO	C4993 C5036		60	5
			Entecavir GH	C4993 C5036		60	5
			Entecavir Mylan	C4993 C5036		60	5
			ENTECAVIR RBX	C4993 C5036		60	5
			Entecavir Sandoz	C4993 C5036		60	5
			Entecavir Viartis	C4993 C5036		60	5
			ENTECLUDE	C4993 C5036		60	5
	Tablet 1 mg (as monohydrate)	Oral	ENTECAVIR APO	C5037 C5044		60	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Entecavir Mylan	C5037 C5044		60	5
			ENTECAVIR RBX	C5037 C5044		60	5
			Entecavir Sandoz	C5037 C5044		60	5
			Entecavir Viatrix	C5037 C5044		60	5
			ENTECLUDE	C5037 C5044		60	5
Epoetin Alfa	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 1000	C6294 C9688		12	5
	Injection 2,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 2000	C6294 C9688		12	5
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Eprex 3000	C6294 C9688		12	5
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Eprex 4000	C6294 C9688		12	5
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 5000	C6294 C9688		12	5
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Eprex 6000	C6294 C9688		12	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Eprex 8000	C6294 C9688		12	5
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Eprex 10000	C6294 C9688		12	5
	Injection 20,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 20,000	C6294 C9688		12	5
	Injection 40,000 units in 1 mL pre-filled syringe	Injection	Eprex 40,000	C6294 C9688		2	5
Epoetin Beta	Injection 2,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	C6294 C9688		12	5
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	C6294 C9688		12	5
	Injection 4,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	C6294 C9688		12	5
	Injection 5,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	C6294 C9688		12	5
	Injection 6,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	C6294 C9688		12	5
	Injection 10,000 units in 0.6 mL pre-filled syringe	Injection	NeoRecormon	C6294 C9688		12	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Epoetin lambda	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 2,000 units in 1 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Novicrit	C6294 C9688		12	5
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection	Veletri	C13491 C13505 C13506 C13510 C13512 C13577 C13634		See Schedule 2	See Schedule 2
	Powder for I.V. infusion 500	Injection	Flolan	C13491 C13505 C13506		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	micrograms (as sodium) with 2 vials diluent 50 mL			C13510 C13512 C13577 C13634			
	Powder for I.V. infusion 1.5 mg (as sodium)	Injection	Veletri	C13491 C13505 C13506 C13510 C13512 C13577 C13634		See Schedule 2	See Schedule 2
	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection	Flolan	C13491 C13505 C13506 C13510 C13512 C13577 C13634		See Schedule 2	See Schedule 2
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	C9417 C14068 C14070 C14071 C14154 C14155		See Schedule 2	See Schedule 2
	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	C9417 C14068 C14070 C14071 C14154 C14155		See Schedule 2	See Schedule 2
	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	C9417 C14068 C14070 C14071 C14154 C14155		See Schedule 2	See Schedule 2
Etravirine	Tablet 200 mg	Oral	Intelence	C5014		120	5
Everolimus	Tablet 0.25 mg	Oral	Certican	C5554 C5795 C9691 C9693		120	5
			Everocan	C5554 C5795 C9691 C9693		120	5
	Tablet 0.5 mg	Oral	Certican	C5554 C5795 C9691 C9693		120	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Filgrastim	Tablet 0.75 mg	Oral	Everocan	C5554 C5795 C9691 C9693		120	5
			Certican	C5554 C5795 C9691 C9693		240	5
			Everocan	C5554 C5795 C9691 C9693		240	5
	Tablet 1 mg	Oral	Certican	C5554 C5795 C9691 C9693		240	5
			Everocan	C5554 C5795 C9691 C9693		240	5
			Nivestim	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
	Injection 300 micrograms in 0.5 mL single-use pre-filled syringe	Injection	Nivestim	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
			Zarzio	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 480 micrograms in 0.5 mL single-use pre-filled syringe	Injection	Nivestim	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
			Zarzio	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
Ganciclovir	Powder for I.V. infusion 500 mg (as sodium)	Injection	Cymevene	C4972 C4999 C5000 C9404 C9526		10	1
			GANCICLOVIR SXP	C4972 C4999 C5000 C9404 C9526		10	1
Glecaprevir with pibrentasvir	Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir	Oral	Maviret	C7593 C7615 C10268	P7593	84	1
				C7593 C7615 C10268	P7615	84	2
				C7593 C7615 C10268	P10268	84	3
Iloprost	Solution for inhalation 20 micrograms (as trometamol)	Inhalation	Ventavis	C13491 C13505 C13506 C13510 C13577 C13631		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	in 2 mL			C13634			
Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	C4524 C7777 C8296 C8844 C8881 C8883-C8940 C8941 C8962 C9065 C9067 C9068 C9111 C9188 C9472 C9559 C9584 C9602 C9632 C9668 C9669 C9677 C9719 C9721 C9732 C9751 C9754 C9775 C9779 C9783 C9787 C9803 C11158 C12003 C12025 C12042 C12043 C12049 C12051 C12059 C12063 C12069 C12074 C12313 C13518 C13526 C13584 C13586 C13587 C13639 C13640 C13641 C13691 C13692 C13702 C13719 C14359 C14360 C14502 C14504 C14505 C14507 C14544 C14546 C14547 C14548 C14585 C14597 C14615 C14623 C14638 C14667 C14683 C14689	See Schedule 2	See Schedule 2	

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
				C14701 C14705 C14707 C14716 C14718 C14723 C14724 C14737			
			Remicade	C4524 C7777 C8296 C8881 C8883 C8941 C8962 C9065 C9067 C9068 C9111 C9559 C9632 C9669 C9677 C9719 C9721 C9751 C9754 C9779 C9783 C9803 C11158 C12003 C12025 C12043 C12049 C12059 C12063 C12313 C13518 C13526 C13584 C13586 C13587 C13639 C13640 C13641 C13691 C13692 C13702 C13719 C14359 C14360 C14504 C14505 C14507 C14546 C14547 C14548 C14597 C14615 C14667 C14705 C14716 C14718 C14724 C14737		See Schedule 2	See Schedule 2
			Renflexis	C4524 C7777 C8296 C8844 C8881 C8883-C8940 C8941		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
				C8962 C9065 C9067 C9068			
				C9111 C9188 C9472 C9559			
				C9584 C9602 C9632 C9668			
				C9669 C9677 C9719 C9721			
				C9732 C9751 C9754 C9775			
				C9779 C9783 C9787 C9803			
				C11158 C12003 C12025			
				C12042 C12043 C12049			
				C12051 C12059 C12063			
				C12069 C12074 C12313			
				C13518 C13526 C13584			
				C13586 C13587 C13639			
				C13640 C13641 C13691			
				C13692 C13702 C13719			
				C14359 C14360 C14502			
				C14504 C14505 C14507			
				C14544 C14546 C14547			
				C14548 C14585 C14597			
				C14615 C14623 C14638			
				C14667 C14683 C14689			
				C14701 C14705 C14707			
				C14716 C14718 C14723			
				C14724 C14737			

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Interferon Gamma-1b	Injection 2,000,000 I.U. in 0.5 mL	Injection	Imukin	C6222 C9639		12	11
Ivacaftor	Sachet containing granules 25 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255		See Schedule 2	See Schedule 2
	Sachet containing granules 50 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255		See Schedule 2	See Schedule 2
	Sachet containing granules 75 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255		See Schedule 2	See Schedule 2
	Tablet 150 mg	Oral	Kalydeco	C15251 C15252 C15253 C15255		See Schedule 2	See Schedule 2
Lamivudine	Oral solution 10 mg per mL, 240 mL	Oral	3TC	C4454 C4512		8	5
	Tablet 100 mg	Oral	Zeffix	C4993 C5036		56	5
			Zetlam	C4993 C5036		56	5
	Tablet 150 mg	Oral	3TC	C4454 C4512		120	5
			Lamivudine Alphapharm	C4454 C4512		120	5
	Tablet 300 mg	Oral	3TC	C4454 C4512		60	5

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Lamivudine Alphapharm	C4454 C4512		60	5
Lamivudine with Zidovudine	Tablet 150 mg-300 mg	Oral	Combivir	C4454 C4512		120	5
			Lamivudine/Zidovudine Viatrix 150/300	C4454 C4512		120	5
Lanreotide	Injection 60 mg (as acetate) in single dose pre-filled syringe	Injection	Mytolac	C4575 C7025 C7509 C7532 C9260 C9261		2	5
			Somatuline Autogel	C4575 C7025 C7509 C7532 C9260 C9261		2	5
	Injection 90 mg (as acetate) in single dose pre-filled syringe	Injection	Mytolac	C4575 C7025 C7509 C7532 C9260 C9261		2	5
			Somatuline Autogel	C4575 C7025 C7509 C7532 C9260 C9261		2	5
	Injection 120 mg (as acetate) in single dose pre-filled syringe	Injection	Mytolac	C4575 C7025 C7509 C7532 C9260 C9261 C10061 C10075 C10077		2	5
			Somatuline Autogel	C4575 C7025 C7509 C7532 C9260 C9261 C10061 C10075 C10077		2	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Lanthanum	Tablet, chewable, 500 mg (as carbonate hydrate)	Oral	Fosrenol	C5530 C9762		180	5
	Tablet, chewable, 750 mg (as carbonate hydrate)	Oral	Fosrenol	C5530 C9762		180	5
	Tablet, chewable, 1000 mg (as carbonate hydrate)	Oral	Fosrenol	C5530 C9762		180	5
Lenalidomide	Capsule 5 mg	Oral	Cipla Lenalidomide	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalide	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Dr.Reddy's	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Lenalidomide	C13782 C13785 C13786		See Schedule 2	See Schedule 2
			Sandoz	C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362			
			Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Viatrix	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Revlimid	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Capsule 10 mg	Oral	Cipla Lenalidomide	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalide	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Dr.Reddy's	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Sandoz	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Viatrix	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Revlimid	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
	Capsule 15 mg	Oral	Cipla Lenalidomide	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Lenalide	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Dr.Reddy's	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Sandoz	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Viatris	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Revlimid	C13782 C13785 C13786 C13787 C13791 C13803 C13804 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
	Capsule 25 mg	Oral	Cipla Lenalidomide	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalide	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Dr.Reddy's	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Sandoz	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Lenalidomide-Teva	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Lenalidomide Viatrix	C13782 C13785 C13786 C13787 C13791 C13801 C13803 C13804 C13805 C13810 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
			Revlimid	C13782 C13785 C13786 C13787 C13803 C13805 C13811 C13812 C13813 C14362		See Schedule 2	See Schedule 2
Levodopa with carbidopa	Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL	Intra-intestinal	Duodopa	C10138 C10161 C10363 C10375	P10138 P10161	28	5
				C10138 C10161 C10363 C10375	P10363 P10375	56	5
Lipegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Lonquex	C7822 C7843 C9224 C9322		1	11

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Lopinavir with ritonavir	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	Oral	Kaletra	C4454 C4512		10	5
	Tablet 200 mg-50 mg	Oral	Kaletra	C4454 C4512		240	5
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 75 mg and ivacaftor 94 mg	Oral	Orkambi	C14757 C14765		See Schedule 2	See Schedule 2
	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral	Orkambi	C14757 C14765		See Schedule 2	See Schedule 2
	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral	Orkambi	C14757 C14765		See Schedule 2	See Schedule 2
	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral	Orkambi	C14783 C14784		See Schedule 2	See Schedule 2
	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral	Orkambi	C14785 C14796		See Schedule 2	See Schedule 2
Macitentan	Tablet 10 mg	Oral	Opsumit	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth	Bronchitol	C7362 C7367 C9527 C9593		4	5
Maraviroc	Tablet 150 mg	Oral	Celsentri	C5008		120	5
	Tablet 300 mg	Oral	Celsentri	C5008		120	5
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen	Injection	Nucala	C13865 C13890 C15344 C15353 C15376 C15400		See Schedule 2	See Schedule 2
	Powder for injection 100 mg	Injection	Nucala	C15344 C15353 C15376 C15400		See Schedule 2	See Schedule 2
Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL	Oral	Aspen Methadone Syrup	C15358		840	5
			Biodone Forte	C15358		840	5
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL	Oral	Aspen Methadone Syrup	C15358		840	5
Methoxsalen	Solution for blood fraction 20 microgram per mL, 10 mL	Extracorporeal Circulation	Uvadex	C10971 C10985 C10988	P10988	1	5
				C10989 C12531 C12546 C12567 C12579	P10989		

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
				C10971 C10985 C10988 C10989 C12531 C12546 C12567 C12579	P12531 P12567	2	0
				C10971 C10985 C10988 C10989 C12531 C12546 C12567 C12579	P10971 P10985	2	6
				C10971 C10985 C10988 C10989 C12531 C12546 C12567 C12579	P12546 P12579	12	1
Methoxy polyethylene glycol-epoetin beta	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5
	Injection 50 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5
	Injection 75 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5
	Injection 100 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5
	Injection 120 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 200 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5
	Injection 360 micrograms in 0.6 mL pre-filled syringe	Injection	Mircera	C6294 C9688		2	5
Midostaurin	Capsule 25 mg	Oral	Rydapt	C11699 C13001 C13013		See Schedule 2	See Schedule 2
Mycophenolic acid	Capsule containing mycophenolate mofetil 250 mg	Oral	APO-Mycophenolate	C5600 C5653 C9689 C9690		600	5
			CellCept	C5600 C5653 C9689 C9690		600	5
			Ceptolate	C5600 C5653 C9689 C9690		600	5
			Mycophenolate Sandoz	C5600 C5653 C9689 C9690		600	5
			Pharmacor Mycophenolate 250	C5600 C5653 C9689 C9690		600	5
			CellCept	C5554 C5795 C9691 C9693		2	5
	Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL	Oral	Pharmacor Mycophenolate	C5554 C5795 C9691 C9693		2	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet containing mycophenolate mofetil 500 mg	Oral	ARX-MYCOPHENOLATE	C5554 C5795 C9691 C9693		300	5
			CellCept	C5554 C5795 C9691 C9693		300	5
			Ceptolate	C5554 C5795 C9691 C9693		300	5
			MycoCept	C5554 C5795 C9691 C9693		300	5
			Mycophenolate APOTEX	C5554 C5795 C9691 C9693		300	5
			Mycophenolate GH	C5554 C5795 C9691 C9693		300	5
			Mycophenolate Sandoz	C5554 C5795 C9691 C9693		300	5
			Pharmacor Mycophenolate 500	C5554 C5795 C9691 C9693		300	5
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid	Oral	Mycophenolic Acid ARX	C4084 C4095 C9692 C9809		240	5
			Myfortic	C4084 C4095 C9692 C9809		240	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	Mycophenolic Acid ARX	C4084 C4095 C9692 C9809		240	5
			MYCOTEX	C4084 C4095 C9692 C9809		240	5
			Myfortic	C4084 C4095 C9692 C9809		240	5
Natalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Tysabri	C13625 C13718		2	5
	Solution concentrate for I.V. infusion 300 mg in 15 mL	Injection	Tysabri	C13625 C13718		1	5
Nevirapine	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	Oral	Viramune	C4454 C4512		10	5
	Tablet 200 mg	Oral	Nevirapine Alphapharm	C4454 C4512		120	5
			Nevirapine Viatrix	C4454 C4512		120	5
	Tablet 400 mg (extended release)	Oral	Viramune XR	C4454 C4526		60	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Nivolumab with relatlimab	Solution concentrate for I.V. infusion containing 240 mg nivolumab and 80 mg relatlimab in 20 mL	Injection	Opdualag	C14812 C14815 C14819 C14829	P14812 P14819	2	8
				C14812 C14815 C14819 C14829	P14815 P14829	2	11
Nusinersen	Solution for injection 12 mg in 5 mL	Injection	Spinraza	C12672 C12676 C13222 C13270 C14370 C14421 C14433 C14459 C15066 C15069 C15112 C15116		See Schedule 2	See Schedule 2
Ocrelizumab	Solution concentrate for I.V. infusion 300 mg in 10 mL	Injection	Ocrevus	C7386 C7699 C9523 C9635		2	0
Octreotide	Injection 50 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide (SUN)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Sandostatin 0.05	C6369 C6390 C8165 C9232 C9233 C9289		90	11
	Injection 50 micrograms (as acetate) in 1 mL (S19A)	Injection	Octreotide Acetate Omega (Canada)	C6369 C6390 C8165 C9232 C9233 C9289		90	11

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 100 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide (SUN)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Sandostatin 0.1	C6369 C6390 C8165 C9232 C9233 C9289		90	11
	Injection 100 micrograms (as acetate) in 1 mL (S19A)	Injection	Octreotide Acetate	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Omega (Canada)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
	Injection 500 micrograms (as acetate) in 1 mL	Injection	Octreotide Acetate	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Omega (Canada)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide GH	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide (SUN)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	Injection	Sandostatin 0.5	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide Depot	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313		2	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Sandostatin LAR	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313		2	5
	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	Injection	Octreotide Depot	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313		2	5
			Sandostatin LAR	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313		2	5
	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	Injection	Octreotide Depot	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313 C10061 C10075 C10077		2	5
			Sandostatin LAR	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313 C10061 C10075 C10077		2	5
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Xolair	C15346 C15347 C15350 C15352 C15376 C15401 C15403		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Xolair	C7046 C7055 C15346 C15347 C15350 C15352 C15376 C15401 C15403		See Schedule 2	See Schedule 2
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
	Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	C12639 C14468 C14469		See Schedule 2	See Schedule 2
Pamidronic Acid	Concentrated injection containing pamidronate disodium 15 mg in 5 mL	Injection	Pamisol	C4433 C9234		4	2
	Concentrated injection containing pamidronate disodium 30 mg in 10 mL	Injection	Pamisol	C4433 C9234		2	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Concentrated injection containing pamidronate disodium 60 mg in 10 mL	Injection	Pamisol	C4433 C9234		1	2
	Concentrated injection containing pamidronate disodium 90 mg in 10 mL	Injection	Pamisol	C4433 C5218 C5291 C9234 C9315 C9335		1	11
Pasireotide	Injection (modified release) 20 mg (as embonate), vial and diluent syringe	Injection	Signifor LAR	C9088 C9089		See Schedule 2	See Schedule 2
	Injection (modified release) 40 mg (as embonate), vial and diluent syringe	Injection	Signifor LAR	C9088 C9089		See Schedule 2	See Schedule 2
	Injection (modified release) 60 mg (as embonate), vial and diluent syringe	Injection	Signifor LAR	C9088 C9089		See Schedule 2	See Schedule 2
Pegcetacoplan	Solution for subcutaneous infusion 1,080 mg in 20 mL	Injection	Empaveli	C13616 C13655 C13710 C13743		See Schedule 2	See Schedule 2
Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Pelgraz	C7822 C7843 C9235 C9303		1	11
			Ziextenzo	C7822 C7843 C9235 C9303		1	11

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Peginterferon alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	C5004 C9603		8	5
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	C5004 C9603		8	5
Pegvisomant	Injection set containing powder for injection 10 mg, 30 and diluent, 30	Injection	Somavert	C7087 C9041		See Schedule 2	See Schedule 2
	Injection set containing powder for injection 15 mg, 30 and diluent, 30	Injection	Somavert	C7087 C9041		See Schedule 2	See Schedule 2
	Injection set containing powder for injection 20 mg, 1 and diluent, 1	Injection	Somavert	C9041		See Schedule 2	See Schedule 2
	Injection set containing powder for injection 20 mg, 30 and diluent, 30	Injection	Somavert	C7087 C9041		See Schedule 2	See Schedule 2
Plerixafor	Injection 24 mg in 1.2 mL	Injection	Mozobil	C4549 C9329		1	1
			Plerixafor ARX	C4549 C9329		1	1
			PLERIXAFOR	C4549 C9329		1	1
			EUGIA				

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Pomalidomide	Capsule 1 mg	Oral	Pomolide	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
			Pomalidomide Sandoz	C13746 C13755		See Schedule 2	See Schedule 2
	Capsule 2 mg	Oral	Pomolide	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
			Pomalidomide Sandoz	C13746 C13755		See Schedule 2	See Schedule 2
			Pomalidomide Sandoz	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
	Capsule 3 mg	Oral	Pomalidomide Sandoz	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
			Pomalyst	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
			Pomolide	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
	Capsule 4 mg	Oral	Pomalidomide Sandoz	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
			Pomalyst	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2
			Pomolide	C13746 C13755 C13757 C13768		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Raltegravir	Tablet 400 mg (as potassium)	Oral	Isentress	C4454 C4512		120	5
	Tablet 600 mg (as potassium)	Oral	Isentress HD	C4454 C4512		120	5
Ravulizumab	Solution concentrate for I.V. infusion 300 mg in 3 mL	Injection	Ultomiris	C13459 C14476 C14477 C14530 C14531 C14565 C14586 C14744 C14746 C14747 C14748 C14749 C14780 C14791 C14797		See Schedule 2	See Schedule 2
	Solution concentrate for I.V. infusion 1,100 mg in 11 mL	Injection	Ultomiris	C13459 C14476 C14477 C14530 C14531 C14565 C14586 C14744 C14746 C14747 C14748 C14749 C14780 C14791 C14797		See Schedule 2	See Schedule 2
Ribavirin	Tablet 200 mg	Oral	Ibavyr	C5957		200	2
Rifabutin	Capsule 150 mg	Oral	Mycobutin	C6350 C6356 C9560 C9622		120	5
Rilpivirine	Tablet 25 mg (as hydrochloride)	Oral	Edurant	C4454 C4512		60	5
Riociguat	Tablet 500 micrograms	Oral	Adempas	C13502 C13514 C13515 C15271 C15272 C15274		See Schedule 2	See Schedule 2
	Tablet 1 mg	Oral	Adempas	C13502 C13514 C13515 C15271 C15272 C15274		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet 1.5 mg	Oral	Adempas	C13502 C13514 C13515 C15271 C15272 C15274		See Schedule 2	See Schedule 2
	Tablet 2 mg	Oral	Adempas	C13502 C13514 C13515 C15271 C15272 C15274		See Schedule 2	See Schedule 2
	Tablet 2.5 mg	Oral	Adempas	C13502 C13514 C13515 C15271 C15272 C15274		See Schedule 2	See Schedule 2
Risdiplam	Powder for oral solution 750 micrograms per mL, 80 mL	Oral	Evrysdi	C14368 C14372 C14392 C14408 C14420 C14435 C14458 C15095		See Schedule 2	See Schedule 2
Ritonavir	Tablet 100 mg	Oral	Norvir	C4454 C4512		720	5
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Riximyo			6	0
			Ruxience			6	0
			Truxima			6	0
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Riximyo			2	1
			Ruxience			2	1
			Truxima			2	1

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Romiplostim	Powder for injection 375 micrograms	Injection	Nplate	C13396 C14098 C14099 C14149		See Schedule 2	See Schedule 2
	Powder for injection 625 micrograms	Injection	Nplate	C13396 C14098 C14099 C14149		See Schedule 2	See Schedule 2
Ruxolitinib	Tablet 5 mg	Oral	Jakavi	C13876 C13892 C13907 C13911	P13907 P13911	56	0
				C13876 C13892 C13907 C13911	P13876 P13892	56	5
	Tablet 10 mg	Oral	Jakavi	C13876 C13892 C13907 C13911	P13907 P13911	56	0
				C13876 C13892 C13907 C13911	P13876 P13892	56	5
Selexipag	Tablet 200 micrograms	Oral	Uptravi	C11193 C11195 C11261		See Schedule 2	See Schedule 2
	Tablet 400 micrograms	Oral	Uptravi	C11193 C11195		See Schedule 2	See Schedule 2
	Tablet 600 micrograms	Oral	Uptravi	C11193 C11195		See Schedule 2	See Schedule 2
	Tablet 800 micrograms	Oral	Uptravi	C11193 C11195 C11261		See Schedule 2	See Schedule 2
	Tablet 1 mg	Oral	Uptravi	C11193 C11195		See Schedule 2	See Schedule 2
	Tablet 1.2 mg	Oral	Uptravi	C11193 C11195		See Schedule 2	See Schedule 2
	Tablet 1.4 mg	Oral	Uptravi	C11193 C11195		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet 1.6 mg	Oral	Uptravi	C11193 C11195		See Schedule 2	See Schedule 2
Selinexor	Tablet 20 mg	Oral	Xpovio	C14021 C14023 C14024	P14021	16	2
				C14031 C14039 C14045	P14045		
				C14021 C14023 C14024	P14023		
				C14031 C14039 C14045	P14024		
Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral	ARX-SEVELAMER	C5530 C9762		360	5
			Sevelamer Apotex	C5530 C9762			
			Sevelamer Lupin	C5530 C9762			
			Renagel	C5530 C9762			
Sildenafil	Tablet 20 mg (as citrate)	Oral	Revatio	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629		See Schedule 2	See Schedule 2
			SILDATIO PHT	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629			

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Sildenafil PHT APOTEX	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629		See Schedule 2	See Schedule 2
			Sildenafil Sandoz PHT 20	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629		See Schedule 2	See Schedule 2
Siltuximab	Powder for injection 100 mg	Injection	Sylvant	C12585 C12594		2	4
	Powder for injection 400 mg	Injection	Sylvant	C12585 C12594		2	4
Sirolimus	Oral solution 1 mg per mL, 60 mL	Oral	Rapamune	C5795 C9914		2	5
	Tablet 0.5 mg	Oral	Rapamune	C5795 C9914		200	5
	Tablet 1 mg	Oral	Rapamune	C5795 C9914		200	5
	Tablet 2 mg	Oral	Rapamune	C5795 C9914		200	5
Sofosbuvir with velpatasvir	Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir	Oral	Epclusa	C5969		28	2
Sofosbuvir with velpatasvir and voxilaprevir	Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir and 100 mg voxilaprevir	Oral	Vosevi	C10248		28	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Sucroferric oxyhydroxide	Tablet, chewable, 2.5 g (equivalent to 500 mg iron)	Oral	Velphoro	C5530 C9762		180	5
Tacrolimus	Capsule 0.5 mg	Oral	Pacrolim	C5569 C9697		200	5
			Pharmacor Tacrolimus 0.5	C5569 C9697		200	5
			Prograf	C5569 C9697		200	5
			Tacrograf	C5569 C9697		200	5
			Tacrolimus Sandoz	C5569 C9697		200	5
	Capsule 0.5 mg (once daily prolonged release)	Oral	ADVAGRAF XL	C5569 C9697		60	5
			Tacrolimus XR Sandoz	C5569 C9697		60	5
	Capsule 0.75 mg	Oral	Tacrolimus Sandoz	C5569 C9697		200	5
	Capsule 1 mg	Oral	Pacrolim	C5569 C9697		200	5
			Pharmacor Tacrolimus 1	C5569 C9697		200	5
Prograf			C5569 C9697		200	5	
Tacrograf			C5569 C9697		200	5	

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Tacrolimus Sandoz	C5569 C9697		200	5
	Capsule 1 mg (once daily prolonged release)	Oral	ADVAGRAF XL	C5569 C9697		120	5
			Tacrolimus XR Sandoz	C5569 C9697		120	5
	Capsule 2 mg	Oral	Tacrolimus Sandoz	C5569 C9697		200	5
	Capsule 3 mg (once daily prolonged release)	Oral	ADVAGRAF XL	C5569 C9697		100	3
			Tacrolimus XR Sandoz	C5569 C9697		100	3
	Capsule 5 mg	Oral	Pharmacor Tacrolimus 5	C5569 C9697		100	5
			Prograf	C5569 C9697		100	5
			Tacrograf	C5569 C9697		100	5
			Tacrolimus Sandoz	C5569 C9697		100	5
	Capsule 5 mg (once daily prolonged release)	Oral	ADVAGRAF XL	C5569 C9697		60	5
			Tacrolimus XR Sandoz	C5569 C9697		60	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Tadalafil	Tablet 20 mg	Oral	Adcirca	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629		See Schedule 2	See Schedule 2
			Tadalca	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629		See Schedule 2	See Schedule 2
			TADALIS 20	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629		See Schedule 2	See Schedule 2
Teduglutide	Powder for injection 5 mg with diluent	Injection	Revestive	C11999 C14534 C14632		See Schedule 2	See Schedule 2
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg	Oral	Tenofovir APOTEX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2
			Tenofovir Sandoz	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2
			Viread	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Tenofovir APOTEX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5
			Tenofovir Sandoz	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5
			Viread	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5
	Tablet containing tenofovir disoproxil maleate 300 mg	Oral	Tenofovir Disoproxil Mylan	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2
			Tenofovir Disoproxil Viatrix	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Tenofovir Disoproxil Mylan	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5
			Tenofovir Disoproxil Viatris	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5
	Tablet containing tenofovir disoproxil phosphate 291 mg	Oral	Tenofovir GH	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2
				C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat	Tablet containing tenofovir alafenamide 10 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	Oral	Genvoya	C4470 C4522		60	5
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	CIPLA TENOFOVIR + EMTRICITABINE 300/200	C6985 C6986		60	5
			Tenofovir/Emtricitabine 300/200 APOTEX	C6985 C6986		60	5
			TENOFOVIR/EMTRICITABINE 300/200 ARX	C6985 C6986		60	5
	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	Oral	Tenofovir Disoproxil Emtricitabine Viartis 300/200	C6985 C6986		60	5
	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	C6985 C6986		60	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg	Oral	Tenofovir/Emtricitabine Sandoz 301/200	C6985 C6986		60	5
Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	Oral	Tenofovir Disoproxil Emtricitabine Efavirenz Viatrix 300/200/600	C4470 C4522		60	5
Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral	Symdeko	C12609 C12614 C12630 C12635		See Schedule 2	See Schedule 2
Thalidomide	Capsule 50 mg	Oral	Thalomid	C5914 C9290		112	0
	Capsule 100 mg	Oral	Thalomid	C5914 C9290		56	0

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Actemra	C9380 C9386 C9407 C9417 C9494 C9495 C10570 C12163 C12436 C12450 C12451 C14082 C14083 C14085 C14091 C14093 C14145 C14148 C14162 C14164 C14179 C14485 C14487 C14488 C14489 C14491 C14507 C14538 C14621		See Schedule 2	See Schedule 2
	Concentrate for injection 200 mg in 10 mL	Injection	Actemra	C9380 C9386 C9407 C9417 C9494 C9495 C10570 C12163 C12436 C12450 C12451 C14082 C14083 C14085 C14091 C14093 C14145 C14148 C14162 C14164 C14179 C14485 C14487 C14488 C14489 C14491 C14507 C14538 C14621		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Concentrate for injection 400 mg in 20 mL	Injection	Actemra	C9380 C9386 C9407 C9417 C9494 C9495 C10570 C12163 C12436 C12450 C12451 C14082 C14083 C14085 C14091 C14093 C14145 C14148 C14162 C14164 C14179 C14485 C14487 C14488 C14489 C14491 C14507 C14538 C14621		See Schedule 2	See Schedule 2
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection	Stelara	C9655 C9656 C9710 C13975 C13976 C14010 C14758 C14787 C14801		See Schedule 2	See Schedule 2
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	APX Valaciclovir	C5975 C9267		500	2
			Valaciclovir APOTEX	C5975 C9267		500	2
			Valaciclovir RBX	C5975 C9267		500	2
			Valtrex	C5975 C9267		500	2
Valganciclovir	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	Oral	Valcyte	C4980 C4989 C9316		11	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Tablet 450 mg (as hydrochloride)	Oral	VALGANCICLOVIR HETERO	C4980 C4989 C9316		120	5
			Valganciclovir Sandoz	C4980 C4989 C9316		120	5
			Valganciclovir Viartis	C4980 C4989 C9316		120	5
Vedolizumab	Powder for injection 300 mg	Injection	Entyvio	C9738 C9771 C12080 C12083 C12135 C12137 C12179 C12219 C12220 C12221		See Schedule 2	See Schedule 2
Zidovudine	Capsule 100 mg	Oral	Retrovir	C4454 C4512		400	5
	Capsule 250 mg	Oral	Retrovir	C4454 C4512		240	5
	Syrup 10 mg per mL, 200 mL	Oral	Retrovir	C4454 C4512		15	5
Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	Injection	Zoledronic Acid Accord	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P14729 P14735	1	0
			APO Zoledronic Acid	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11
			DEZTRON	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11

Schedule 1 HSD pharmaceutical benefits and related information

Clause 1

HSD pharmaceutical benefits and related information

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Zoledronate-DRLA 4	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11
			Zoledronic Acid Accord	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328 C14729 C14735	P5605 P5703 P5704 P5735 P9268 P9304 P9317 P9328	1	11
			Zometa	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11

Schedule 2—Maximum quantities and repeats for certain HSD pharmaceutical benefits

Note: See sections 20 and 21, and the columns headed “Maximum quantity” and “Maximum repeats” in Schedule 1.

1 Maximum quantity or number of units and maximum number of repeats

The following table sets out the maximum quantity or number of units, and the maximum number of repeats, for prescribing HSD pharmaceutical benefits with the listed drugs, and in the circumstances, mentioned in the table.

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
Abatacept	C14488 C14524	1 dose	Sufficient for treatment for 16 weeks
	C14523 C14617	1 dose	4
	C14507 C14519 C14555 C14604	1 dose	Sufficient for treatment for 24 weeks
Adalimumab	C12120 C14061 C14063 C14064	2 doses	3
	C14107 C14136	2 doses	5
Ambrisentan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582	Sufficient for treatment for 1 month	5
Anifrolumab	C15387 C15388 C15426	1	5
Avatrombopag	C14054 C14130 C15340 C15375	30	5
Azacitidine	C12439 C12983 C13010 C13029	14 units	2
	C12986 C13011 C13012 C13015	14 units	5
Benralizumab	C15376 C15383 C15444	1	Sufficient for 32 weeks of treatment
	C15353	1	Sufficient for 24 weeks of treatment

Schedule 2 Maximum quantities and repeats for certain HSD pharmaceutical benefits

Clause 1

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
Bosentan	C11229 C13495 C13496 C13497 C13499 C13571 C13582 C13632	Sufficient for treatment for 1 month	5
	C12425	Sufficient for treatment for 1 month	0
Burosumab	C13330 C13377	Sufficient for treatment for 4 weeks	5
Daunorubicin with cytarabine	C15390	2	3
	C15413	3	4
Difelikefalin	C15171	Sufficient for treatment for 4 weeks	2
	C15211 C15227	Sufficient for treatment for 4 weeks	5
Dupilumab	C15341 C15424 C15425 C15433	1 pack	Sufficient for 32 weeks of treatment
	C15348	1 pack	Sufficient for 24 weeks of treatment
Eculizumab	C14781	Sufficient for treatment for 4 weeks	0
	C13857	1	0
	C14750 C14792	Sufficient for treatment for 4 weeks	4
	C14753 C14754 C14793 C14799 C14805	Sufficient for treatment for 4 weeks	5
	C13464 C13660 C13661 C13684 C13845	6	5
	C13458 C13459 C13560	8	0
Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	C13932 C13962 C13980 C13991	1 pack	5
Eltrombopag	C13327 C14126 C14127 C14129	1 pack	5
	C15192	3 packs	3
	C15173 C15174 C15191	3 packs	5
Epoprostenol	C13491 C13505 C13506 C13510 C13512 C13577 C13634	Sufficient for treatment for 1 month	5
Etanercept	C9417 C14068 C14070 C14071	Sufficient for treatment for 4 weeks	3

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
	C14154 C14155	Sufficient for treatment for 4 weeks	5
Iloprost	C13491 C13505 C13506 C13510 C13577 C13631 C13634	Sufficient for treatment for 1 month	5
Infliximab	C9111 C9559 C11158 C13518 C13584 C13586 C13587 C13640 C13692 C13719 C14359 C14360 C14667 C14683 C14689 C14701 C14705 C14707 C14716 C14718 C14723 C14724 C14737	1 dose of 5 mg per kg of patient weight	3
	C14502 C14544 C14546 C14547 C14548 C14615 C14623	1 dose of 3 mg per kg of patient weight	3
	C8844 C8940 C9188 C9472 C9584 C9602 C9668 C14504 C14505 C14507 C14585 C14597 C14638	1 dose of 3 mg per kg of patient weight	2
	C7777 C8296 C8881 C8883 C8941 C8962 C9065 C9067 C9068 C9669 C9677 C9719 C9721 C9732 C9751 C9754 C9775 C9779 C9783 C9787 C9803 C12003 C12025 C12042 C12043 C12049 C12051 C12059 C12063 C12069 C12074 C12313 C13526 C13639 C13641 C13691 C13702	1 dose of 5 mg per kg of patient weight	2
	C4524 C9632	5 vials	1
Ivacaftor	C15251 C15252 C15253 C15255	1 pack	Sufficient for 24 weeks of treatment
Lenalidomide	C13785 C13811	14 tablets	3
	C13813	21 tablets	1
	C13782 C14362	21 tablets	2
	C13786 C13801 C13810	21 tablets	3
	C13787 C13803 C13805 C13812	21 tablets	5
	C13791 C13804	28 tablets	2
Lumacaftor with ivacaftor	C14757 C14765 C14783 C14784 C14785 C14796	1 pack	5
Macitentan	C11229 C13496 C13497 C13499 C13500 C13575 C13576 C13582	Sufficient for treatment for 1 month	5
Mepolizumab	C15344 C15376 C15400	1	Sufficient for 32 weeks of treatment

Schedule 2 Maximum quantities and repeats for certain HSD pharmaceutical benefits

Clause 1

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
	C15353	1	Sufficient for 24 weeks of treatment
	C13865 C13890	1	5
Midostaurin	C11699 C13001 C13013	1 pack	2
Nusinersen	C14433 C14459 C15069 C15112	1 dose	0
	C12672 C12676 C13222 C13270 C14370 C14421 C15066 C15116	1 dose	3
Omalizumab	C7055	2	2
	C7046	2	5
	C15347 C15352	1	Sufficient for 24 weeks of treatment
	C15346 C15376 C15401	1	Sufficient for 32 weeks of treatment
	C15350 C15403	1	Sufficient for 28 weeks of treatment
Onasemnogene abeparvovec	C12639 C14468 C14469	1 dose	0
Pasireotide	C9088 C9089	2	5
Pegcetacoplan	C13655 C13710	Sufficient for treatment for 4 weeks	0
	C13616 C13743	Sufficient for treatment for 4 weeks	5
Pegvisomant	C7087 C9041	1	5
Pomalidomide	C13757 C13768	1 pack (14 capsules)	2
	C13746 C13755	1 pack (21 capsules)	0
Ravulizumab	C13459 C14477 C14565 C14586 C14744 C14780 C14791 C14797	1 dose	0
	C14476 C14530 C14531 C14746 C14747 C14748 C14749	1 dose	2
Riociguat	C15274	Sufficient for treatment for 1 month	3
	C13514 C13515	Sufficient for treatment for 1 month	4

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
	C13502 C15271 C15272	Sufficient for treatment for 1 month	5
Risdiplam	C14372 C14435 C14458	1	0
	C15095	1	5
	C14392 C14408 C14420	3	5
	C14368	3	7
Romiplostim	C14098	1 vial	5
	C13396 C14099	Sufficient for treatment for 4 weeks	5
	C14149	1 vial	Sufficient for treatment for 24 weeks
Selexipag	C11193 C11195	60	5
	C11261	140	Sufficient for treatment for 12 weeks
Sildenafil	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629	Sufficient for treatment for 1 month	5
Tadalafil	C11229 C13482 C13484 C13569 C13570 C13572 C13573 C13629	Sufficient for treatment for 1 month	5
Teduglutide	C14632	1 pack	5
	C11999 C14534	1 pack	11
Tezacaftor with Ivacaftor and Ivacaftor	C12609 C12614 C12630 C12635	1 pack	5
Tocilizumab	C9386 C9407 C9417 C9494 C12163 C12436 C12450 C12451 C14083 C14145 C14162 C14487 C14488 C14491 C14507 C14538	1 infusion	3
	C10570 C14085 C14091 C14148	2 infusions	3
	C9380 C9495 C14082 C14164 C14485 C14489 C14621	1 infusion	5
	C14093 C14179	2 infusions	5
Ustekinumab	C9655 C9656 C9710 C13975 C13976 C14010 C14758 C14787 C14801	4 vials (130 mg each)	0

Schedule 2 Maximum quantities and repeats for certain HSD pharmaceutical benefits

Clause 1

Maximum quantity or number of units, and maximum number of repeats			
Listed drug	Circumstances	Maximum quantity	Maximum repeats
Vedolizumab	C12080 C12083 C12135 C12137 C12179 C12219 C12220 C12221	1	2
	C9738 C9771	1	Sufficient for treatment for 24 weeks

Schedule 3—Circumstances and purposes

Note: See sections 13, 15, 16, 20 and 21.

1 Circumstances and purposes

The following table sets out circumstances and purposes for circumstances codes and purposes codes.

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
Abacavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
	C13920		Human immunodeficiency virus (HIV) infection Patient must be less than 13.00 years of age. Patient must be unable to take a solid dose form of this drug; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures
Abacavir with Lamivudine	C4527		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Authority Required procedures - Streamlined Authority Code 4527
	C4528		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND	Compliance with Authority Required procedures - Streamlined

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			The treatment must be in combination with other antiretroviral agents; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Authority Code 4528
Abatacept	C14488		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C14507		Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures
	C14519		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a</p>	

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14523		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.</p> <p>Up to a maximum of 4 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
	C14524		Severe active rheumatoid arthritis	Compliance with Written

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the</p>	Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14555		<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as:</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline,</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14555

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	
	C14604		<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as:</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14604

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	
	C14617		<p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous</p>	Compliance with Written Authority Required procedures

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialed at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority</p>	

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			<p>application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.</p> <p>Up to a maximum of 4 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced</p>	

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			a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
Adalimumab	C12120		Severe active juvenile idiopathic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C14061		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Authority Required procedures

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			<p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14063		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p>	Compliance with Authority Required procedures

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			<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Active joints are defined as:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to</p>	

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			receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14064		<p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response and must be demonstrated</p>	Compliance with Authority Required procedures

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			<p>in all patients at the time of the initial application:</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C14107		<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14107

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			<p>authorised under this restriction.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14136		<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14136</p>

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			<p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
Adefovir	C4490		<p>Chronic hepatitis B infection</p> <p>Patient must not have cirrhosis; AND</p> <p>Patient must have failed antihepadnaviral therapy; AND</p> <p>Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR</p> <p>Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4490

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			failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	
	C4510		Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4510
Alemtuzumab	C6847	P6847	Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6847
	C7714	P7714	Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 7714

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	C9589	P9589	Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9589
	C9636	P9636	Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9636
Ambrisentan	C11229		Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to	Compliance with Authority Required procedures

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			<p>the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>The authority application for selexipag must be approved prior to the authority application for this agent.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or</p> <p>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13496		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination</p>	Compliance with Written Authority Required procedures

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			<p>therapy is treating a patient with class IV PAH.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. 	

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			(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current. (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application.	
	C13497		Pulmonary arterial hypertension (PAH) Initial 3 - changing to this drug in combination therapy (dual or triple therapy) The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.	Compliance with Authority Required procedures
	C13499		Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.	Compliance with Authority Required procedures
	C13500		Pulmonary arterial hypertension (PAH) Initial 1 (new patients)	Compliance with Written Authority Required

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			<p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is: - ECHO composite assessment plus 6MWT; - ECHO composite assessment only.</p>	procedures

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			<p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13575		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C13576		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition</p>	Compliance with Authority Required procedures

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			<p>with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13582		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination</p>	Compliance with Authority Required procedures

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			therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.	
Anakinra	C5450		Moderate to severe cryopyrin associated periodic syndromes (CAPS) Must be treated by a rheumatologist or in consultation with a rheumatologist; OR Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 5450
Anifrolumab	C15387		Systemic lupus erythematosus Continuing or recommencement of treatment (within 12 months of a treatment break) Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must be responding to treatment if they have received less than 12 months of treatment with this drug for this condition; OR Patient must have attained a Lupus Low Disease Activity State (LLDAS) and maintained this state while on treatment. Must be treated by a specialist physician experienced in the management of this condition. Lupus Low Disease Activity State (LLDAS) is defined as: (a) Total SLEDAI-2K of not greater than 4, with no major activity in major organ systems (renal, central nervous system (CNS), cardiopulmonary, vasculitis, fever); and (b) No new features of lupus disease activity compared with the previous assessment, and (c) Physician Global Assessment (PGA) of not greater than 1, and (d) Current prednisolone (or equivalent) dose of not greater than 7.5 mg daily, and (e) Well tolerated standard maintenance doses of anti-malarial and immunosuppressive drugs are allowed. Where retreatment with anifrolumab after a break in PBS-subsidised treatment with anifrolumab is being sought, the date of cessation of the previous treatment course with anifrolumab must be included in the application. Recommencement of treatment with anifrolumab for severe SLE is within 12 months from the date that treatment was ceased.	Compliance with Authority Required procedures
	C15388		Systemic lupus erythematosus Initial treatment Patient must have a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019; AND	Compliance with Written Authority Required procedures

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			<p>Patient must have persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points; AND</p> <p>Patient must be currently receiving hydroxychloroquine, with treatment received for at least 12 weeks, unless contraindicated/intolerant necessitating treatment withdrawal; AND</p> <p>Patient must be currently receiving immunosuppressant medication, with treatment received for at least 12 weeks, with either: (i) minimum dose of methotrexate 20 mg per week, (ii) azathioprine 100 mg per day, (iii) mycophenolate 1,000 mg per day unless contraindicated/intolerant necessitating treatment withdrawal; AND</p> <p>Patient must be currently receiving prednisolone or equivalent of at least 7.5 mg per day, with treatment received for at least 4 weeks, unless contraindicated/intolerant necessitating treatment withdrawal; AND</p> <p>Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus.</p> <p>Must be treated by a specialist physician experienced in the management of this condition.</p> <p>If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.</p> <p>Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.</p> <p>If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.</p> <p>The authority application must be made in writing via HPOS form upload or mail and must include:</p> <ul style="list-style-type: none"> (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE; (b) details (date and score) of the completed SLEDAI-2K score sheet; (c) details of current systemic therapy used (dosage, date of commencement and duration of 	

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			<p>therapy including prior anifrolumab use); (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose). All the reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C15426		<p>Systemic lupus erythematosus Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2024; AND Patient must have had a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019 prior to commencing therapy with this drug for this condition; AND Patient must have had persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points prior to commencing therapy with this drug for this condition; AND Patient must have been receiving hydroxychloroquine for at least 12 weeks prior to commencing therapy with this drug for this condition; AND Patient must have been receiving immunosuppressant medication for at least 12 weeks with either (i) minimum dose of methotrexate 20 mg per week (ii) azathioprine 100 mg per day (iii) mycophenolate 1,000 mg per day, prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal; AND Patient must have been receiving prednisolone or equivalent of at least 7.5 mg per day for at least 4 weeks prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal; AND Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus. Must be treated by a specialist physician experienced in the management of this condition. If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated of at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii)</p>	Compliance with Written Authority Required procedures

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			<p>azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.</p> <p>Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.</p> <p>If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.</p> <p>The authority application must be made in writing via HPOS form upload or mail and must include:</p> <ul style="list-style-type: none"> (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE; (b) details (date and score) of the completed SLEDAI-2K score sheet; (c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use); (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose). <p>All the reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <ul style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>	
Apomorphine	C10830		<p>Parkinson disease</p> <p>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND</p> <p>The treatment must be commenced in a specialist unit in a hospital setting.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10830
	C10863		<p>Parkinson disease</p> <p>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND</p> <p>The treatment must be commenced in a specialist unit in a hospital setting.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10863

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	C11385		Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 11385
	C11445		Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 11445
Atazanavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Atazanavir with cobicistat	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Avatrombopag	C14054		Severe thrombocytopenia Second or Subsequent Continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction; AND Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.	Compliance with Authority Required procedures

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			The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.	
	C14130		<p>Severe thrombocytopenia Initial treatment - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details of a platelet count supporting the diagnosis of ITP. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.</p>	Compliance with Written Authority Required procedures
	C15340		<p>Severe thrombocytopenia Balance of supply or change of therapy The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR Patient must have received insufficient therapy with this drug for this condition under the First</p>	Compliance with Authority Required procedures

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			Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition; AND The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction. Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.	
	C15375		Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; OR Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment. The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.	Compliance with Authority Required procedures
Azacitidine	C12439		Acute Myeloid Leukaemia The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).	Compliance with Authority Required procedures
	C12983		Myelodysplastic syndrome Initial treatment The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report	Compliance with Authority Required procedures

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			<p>and full blood examination; AND The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations: a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias. Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations: a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias. The following information must be provided by the prescriber at the time of application: (a) The patient's International Prognostic Scoring System (IPSS) score The following reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (b) full blood examination report; and (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease</p>	

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			according to the International Prognostic Scoring System (IPSS). No more than 3 cycles will be authorised under this restriction in a patient's lifetime.	
	C12986		Acute Myeloid Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease.	Compliance with Authority Required procedures - Streamlined Authority Code 12986
	C13010		Acute Myeloid Leukaemia Initial treatment The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification. The following reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and (b) full blood examination report.	Compliance with Authority Required procedures
	C13011		Myelodysplastic syndrome Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
	C13012		Acute Myeloid Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease.	Compliance with Authority Required procedures - Streamlined Authority Code 13012
	C13015		Chronic Myelomonocytic Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures

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	C13029		<p>Chronic Myelomonocytic Leukaemia Initial treatment The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder. The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following reports must be documented in the patient's medical records: (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) full blood examination report No more than 3 cycles will be authorised under this restriction in a patient's lifetime.</p>	Compliance with Written Authority Required procedures
Azithromycin	C6356		<p>Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6356
	C9604		<p>Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9604
Baclofen	C6911		<p>Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR</p>	Compliance with Authority Required

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			Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	procedures - Streamlined Authority Code 6911
	C6925		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 6925
	C6939		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 6939
	C6940		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 6940
	C7134		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 7134
	C7148		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 7148
	C7152		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 7152
	C7153		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 7153
	C9488		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND	Compliance with Authority Required procedures - Streamlined

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			Patient must have chronic spasticity of cerebral origin.	Authority Code 9488
	C9489		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 9489
	C9524		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9524
	C9525		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 9525
	C9562		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 9562
	C9606		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9606
	C9637		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 9637
	C9638		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 9638
Benralizumab	C15353		Uncontrolled severe asthma Continuing treatment Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical	Compliance with Written Authority Required procedures

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			<p>immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 12 years or older.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.</p> <p>All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>Where treatment was ceased for clinical reasons despite the patient experiencing improvement,</p>	

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			<p>an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.</p> <p>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) if applicable, details of maintenance oral corticosteroid dose; and</p> <p>(b) a completed Asthma Control Questionnaire (ACQ-5) score.</p>	
	C15376		<p>Uncontrolled severe asthma</p> <p>Balance of supply</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must not provide more than the balance of up to 32 weeks of treatment if the most</p>	Compliance with Authority Required procedures

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			recent authority approval was made under an Initial treatment restriction; OR The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.	
	C15383		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological</p>	Compliance with Written Authority Required procedures

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			<p>medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (date and duration of treatment) of prior biological medicine treatment; and (c) eosinophil count and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and 	

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			(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	
	C15444		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving</p>	Compliance with Written Authority Required procedures

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			<p>treatment with oral corticosteroids in the last 12 months; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that</p>	

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			<p>there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p>	

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			(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and (b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) the eosinophil count and date; and (e) Asthma Control Questionnaire (ACQ-5) score.	
Bictegravir with emtricitabine with tenofovir alafenamide	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Bosentan	C11229		Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'). Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The authority application for selexipag must be approved prior to the authority application for this agent.	Compliance with Authority Required procedures

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			<p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C12425		<p>Pulmonary arterial hypertension (PAH) Cessation of treatment (all patients) Patient must be receiving PBS-subsidised treatment with this PAH agent; AND The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.</p>	Compliance with Authority Required procedures
	C13495		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures

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			<p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.</p> <p>Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.</p>	
	C13496		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin</p>	Compliance with Written Authority Required procedures

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			<p>receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document</p>	

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			<p>that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p>	
	C13497		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.</p>	Compliance with Authority Required procedures
	C13499		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C13571		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C13582		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures

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	C13632		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>- ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current. (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.</p>	
Buprenorphine	C15355		<p>Opioid dependence The treatment must be within a framework of medical, social and psychological treatment. A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15355
	C15356		<p>Opioid dependence</p>	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a health care professional.</p> <p>The treatment must be within a framework of medical, social and psychological treatment; AND</p> <p>Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.</p> <p>A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	procedures - Streamlined Authority Code 15356
	C15385		<p>Opioid dependence</p> <p>Must be treated by a health care professional.</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p> <p>A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15385
	C15439		<p>Opioid dependence</p> <p>Must be treated by a health care professional.</p> <p>The treatment must be within a framework of medical, social and psychological treatment; AND</p> <p>Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.</p> <p>A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15439
Buprenorphine with naloxone	C15355		<p>Opioid dependence</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p> <p>A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15355
Burosumab	C13330		<p>X-linked hypophosphataemia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>AND</p> <p>Patient must have achieved normalisation in serum phosphate levels; AND</p> <p>Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.</p> <p>Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.</p> <p>Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI).</p> <p>A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	
	C13377		<p>X-linked hypophosphataemia</p> <p>Initial treatment - New patient</p> <p>Patient must have a documented confirmation of PHEX pathogenic variant; OR</p> <p>Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.</p> <p>Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI).</p> <p>A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's</p>	Compliance with Authority Required procedures

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			medical records.	
Cabotegravir	C12619		HIV infection Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND The treatment must be in combination with rilpivirine tablets; AND Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine.	Compliance with Authority Required procedures - Streamlined Authority Code 12619
Cabotegravir and rilpivirine	C12636		HIV infection Patient must have previously received PBS-subsidised therapy for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12636
Ciclosporin	C6628		Management of transplant rejection The treatment must be used by organ or tissue transplant recipients.	Compliance with Authority Required procedures - Streamlined Authority Code 6628
	C6631		Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; OR Patient must be intolerant to treatment with steroids and cytostatic drugs; OR The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment. Must be treated by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6631
	C6638		Severe active rheumatoid arthritis Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6638

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C6643		Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 6643
	C6660		Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies.	Compliance with Authority Required procedures - Streamlined Authority Code 6660
	C9694		Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; OR Patient must be intolerant to treatment with steroids and cytostatic drugs; OR The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment. Must be treated by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9694
	C9695		Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies.	Compliance with Authority Required procedures - Streamlined Authority Code 9695
	C9742		Severe active rheumatoid arthritis Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9742

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	C9764		Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9764
	C9831		Management of transplant rejection The treatment must be used by organ or tissue transplant recipients.	Compliance with Authority Required procedures - Streamlined Authority Code 9831
	C15360		Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar. For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 15360
	C15361		Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist,	Compliance with Authority Required procedures - Streamlined Authority Code 15361

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			(iii) general physician; OR Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar. For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	
Cinacalcet	C10063		Secondary hyperparathyroidism Continuing treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	Compliance with Authority Required procedures - Streamlined Authority Code 10063
	C10067		Secondary hyperparathyroidism Continuing treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	Compliance with Authority Required procedures - Streamlined Authority Code 10067
	C10073		Secondary hyperparathyroidism	Compliance with

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			<p>Initial treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have failed to respond to conventional therapy; AND Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L. During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.</p>	Authority Required procedures
Clozapine	C4998		<p>Schizophrenia Continuing treatment Must be treated by a psychiatrist; OR Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist. Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND Patient must have completed at least 18 weeks therapy; AND Patient must be on a clozapine dosage considered stable by a treating psychiatrist; AND The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4998
	C5015		<p>Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5015

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			The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	
	C9490		Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 9490
Darbepoetin Alfa	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Darunavir	C4313		Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND The treatment must be co-administered with 100 mg ritonavir, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, AND Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 4313
	C5094		Human immunodeficiency virus (HIV) infection	Compliance with

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			The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND The treatment must be co-administered with 100 mg ritonavir twice daily, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Authority Required procedures - Streamlined Authority Code 5094
Darunavir with cobicistat	C6377		Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 6377
	C6413		Human immunodeficiency virus (HIV) infection Initial treatment Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir.	Compliance with Authority Required procedures - Streamlined Authority Code 6413
	C6428		Human immunodeficiency virus (HIV) infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir.	Compliance with Authority Required procedures - Streamlined Authority Code 6428
Darunavir with cobicistat, emtricitabine and tenofovir alafenamide	C10317		HIV infection Continuing treatment Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner. Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must not be in combination with ritonavir.	Compliance with Authority Required procedures - Streamlined Authority Code 10317

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C10324		<p>HIV infection Initial treatment Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner. Patient must be antiretroviral treatment naive; OR Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND The treatment must not be in combination with ritonavir. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10324
Daunorubicin with cytarabine	C15390		<p>Acute Myeloid Leukaemia Consolidation therapy The treatment must be for consolidation treatment following induction treatment with this product; AND The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND The treatment must not exceed two cycles of consolidation therapy under this restriction. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The TGA-approved Product Information recommended dosing schedule for consolidation is daunorubicin 29 mg/m² and cytarabine 65 mg/m² on days 1 and 3. With each authority application, state the body surface area (m²) of the patient. Based on this prescribe up to: 1 vial where the body surface area is between 1 m² to 1.53 m² 2 vials where the body surface area is above 1.53 m² or up to and including 3.07 m²</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C15413		<p>Acute Myeloid Leukaemia Induction therapy Patient must not have received prior chemotherapy as induction therapy for this condition; AND The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND The condition must not be either: (i) internal tandem duplication (ITD); (ii) tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3), mutation positive; AND Patient must not have favourable cytogenetic risk acute myeloid leukaemia (AML); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must not exceed two cycles of induction therapy under this restriction. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The prescriber must confirm whether the patient has newly diagnosed therapy-related AML or AML-MRC. The test result and date of testing must be provided at the time of application and documented in the patient's file. The TGA-approved Product Information recommended dosing schedule is as follows: (i) First Induction: daunorubicin 44 mg/m²and cytarabine 100 mg/m²on days 1, 3 and 5 (ii) Second Induction: daunorubicin 44 mg/m²and cytarabine 100 mg/m²on days 1 and 3 With each authority application, state the body surface area (m²) of the patient. Based on (i) to (ii), prescribe up to: 1 vial where the body surface area is up to and including 1 m²; 2 vials where the body surface area is above 1 m²or up to and including 2 m²; 3 vials where the body surface area is above 2 m²or up to and including 3 m².</p>	Compliance with Authority Required procedures
Deferasirox	C7374	P7374	<p>Chronic iron overload Initial treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C7375	P7375	Chronic iron overload Initial treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis.	Compliance with Authority Required procedures
	C7385	P7385	Chronic iron overload Initial treatment Patient must be red blood cell transfusion dependent; AND Patient must have a serum ferritin level of greater than 1000 microgram/L; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have a median life expectancy exceeding five years.	Compliance with Authority Required procedures
	C8326	P8326	Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8326
	C8328	P8328	Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8328
	C8329	P8329	Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8329
	C9222	P9222	Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9222
	C9258	P9258	Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND	Compliance with Authority Required procedures - Streamlined

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Patient must have a malignant disorder of haemopoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Authority Code 9258
	C9302	P9302	Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9302
Deferiprone	C6403		Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 6403
	C6448		Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6448
	C9228		Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 9228
	C9286		Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9286
	C9590		Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 9590
	C9623		Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9623

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
Desferrioxamine	C6394		Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined Authority Code 6394
	C9696		Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined Authority Code 9696

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
Difelikefalin	C15171		<p>Moderate to severe pruritus (itching) associated with chronic kidney disease</p> <p>Initial treatment</p> <p>Patient must be on optimised haemodialysis; AND</p> <p>Patient must be on haemodialysis for at least 3 months; AND</p> <p>The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; AND</p> <p>Patient must have experienced itch that persists for at least 6 weeks despite best supportive care; AND</p> <p>Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4; AND</p> <p>Patient must not receive more than 12 weeks of treatment under this restriction.</p> <p>Must be treated by a nephrologist.</p> <p>Patient must be at least 18 years of age.</p> <p>Prescriber must exclude any other causes of pruritus which include any of the following:</p> <ul style="list-style-type: none"> (i) drug/dialysis related (e.g., opioid-related pruritus); (ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy; (iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes). <p>Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:</p> <ul style="list-style-type: none"> (i) optimisation of dialysis; (ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils); (iii) patient education on the importance of avoiding or minimising scratching. <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C15211		<p>Moderate to severe pruritus (itching) associated with chronic kidney disease</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.</p> <p>Must be treated by a nephrologist; OR</p> <p>Must be treated by a medical practitioner in consultation with a nephrologist.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C15227		<p>Moderate to severe pruritus (itching) associated with chronic kidney disease Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply was commenced, the patient: (i) was on optimised haemodialysis; (ii) was on haemodialysis for at least 3 months; (iii) had a condition confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; (iv) had experienced itch that persists for at least 6 weeks despite best supportive care; (v) had a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) of more than 4 at baseline; AND Patient must have demonstrated an adequate response to the most recent non-PBS-subsidised treatment with this drug for this condition, including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score. Must be treated by a nephrologist. Patient must be at least 18 years of age. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.</p>	Compliance with Authority Required procedures
Dolutegravir	C4454		<p>HIV infection Continuing Patient must have previously received PBS subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures Streamlined Authority Code 4454
	C4512		<p>HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4512

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
Dolutegravir with abacavir and lamivudine	C9981		HIV infection Initial treatment Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 9981
	C10116		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 10116
Dolutegravir with lamivudine	C9987		HIV infection Initial treatment Patient must be antiretroviral treatment naive; AND Patient must not have suspected resistance to either antiretroviral component.	Compliance with Authority Required procedures - Streamlined Authority Code 9987
	C11066		HIV infection Continuing or change of treatment Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 11066
Dolutegravir with rilpivirine	C8214		HIV infection Initial treatment Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8214
	C8226		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8226
Dornase alfa	C5634		Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to	Compliance with Authority Required procedures - Streamlined Authority Code 5634

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>conventional medicines; OR</p> <p>Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.</p> <p>Patient must be less than 5 years of age.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.</p>	
	C5635		<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Patient must have initiated treatment with dornase alfa at an age of less than 5 years,AND</p> <p>Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.</p> <p>Patient must be 5 years of age or older.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 5635</p>
	C5740		<p>Cystic fibrosis</p> <p>Patient must be 5 years of age or older.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</p> <p>Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.</p> <p>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:</p> <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 5740</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			possibility of harm from unnecessary use.	
	C9591		<p>Cystic fibrosis</p> <p>Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR</p> <p>Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR</p> <p>Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR</p> <p>Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.</p> <p>Patient must be less than 5 years of age.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9591
	C9592		<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Patient must have initiated treatment with dornase alfa at an age of less than 5 years; AND</p> <p>Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.</p> <p>Patient must be 5 years of age or older.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9592
	C9624		<p>Cystic fibrosis</p> <p>Patient must be 5 years of age or older.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9624

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			(FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	
Doxorubicin - Pegylated Liposomal	C6234		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6234
	C6274		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6274
	C9223		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 9223
	C9287		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 9287
Dupilumab	C15341		Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment at around 28 weeks, which will be used to determine eligibility for the first</p>	

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			<p>continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and (c) if applicable, the eosinophil count and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) if applicable, the IgE result and date; and (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy). 	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C15348		<p>Uncontrolled severe asthma</p> <p>Continuing treatment</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 12 years or older.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.</p> <p>All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and, for the application for continuing therapy to be processed.</p> <p>The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided,</p>	Compliance with Written Authority Required procedures

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			<p>the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.</p> <p>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) if applicable, details of maintenance oral corticosteroid dose; and</p> <p>(b) a completed Asthma Control Questionnaire (ACQ-5) score.</p>	
	C15424		<p>Uncontrolled severe asthma</p> <p>Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation; AND</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p>	

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			<p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids as outlined in the clinical criteria.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) Asthma Control Questionnaire (ACQ-5) score; and 	

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			(e) if applicable, the eosinophil count and date; and (f) if applicable, the IgE result and date.	
	C15425		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have each of: (i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, (ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied</p>	Compliance with Written Authority Required procedures

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			<p>by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p>	

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			<p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and</p> <p>(c) if applicable, the eosinophil count and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) if applicable, the IgE result and date; and</p> <p>(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C15433		<p>Uncontrolled severe asthma</p> <p>Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of</p>	Compliance with Written Authority Required procedures

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			<p>greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or</p>	

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			<p>intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for commencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p>	

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			<p>(ii) A pharmacist, nurse or asthma educator.</p> <p>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.</p> <p>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and</p> <p>(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; and</p> <p>(e) if applicable, the eosinophil count and date; and</p> <p>(f) if applicable, the IgE result and date.</p>	
Eculizumab	C13458		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)</p> <p>Patient must be planning pregnancy; OR</p> <p>Patient must be pregnant; AND</p> <p>Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND</p> <p>The treatment must not be in combination with any of (i) ravulizumab, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the</p>	Compliance with Written Authority Required procedures

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			<p>patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	
	C13459		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Return from PBS-subsidised pegcetacoplan - induction doses</p> <p>Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND</p> <p>Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND</p> <p>Patient must have developed resistance or intolerance to pegcetacoplan; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	Compliance with Written Authority Required procedures
	C13464		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase</p> <p>Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; OR</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, details (result and date of result) of the following</p>	

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			monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
	C13560		Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - initial 1 (new patient) induction doses Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m ² , where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii)	Compliance with Written Authority Required procedures

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			<p>pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x109/L)</p> <p>(iii) White Cell Count (x109/L)</p> <p>(iv) Reticulocytes (x109/L)</p> <p>(v) Neutrophils (x109/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
	C13660		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Grandfather 2 (transition from LSDP-funded eculizumab)</p> <p>Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; OR</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months</p>	Compliance with Written Authority Required procedures

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			<p>prior to commencing treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p>	

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			(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
	C13661		Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
	C13684		Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy) Patient must be planning pregnancy; OR Patient must be pregnant; AND Patient must have received PBS-subsidised treatment with ravulizumab for this condition; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent	Compliance with Written Authority Required procedures

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			pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.	
	C13845		<p>Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	Compliance with Written Authority Required procedures
	C13857		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Balance of Supply (transition from non-PBS-subsidised treatment during induction phase) Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have received insufficient quantity to complete the induction treatment phase; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to</p>	Compliance with Written Authority Required procedures

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			<p>commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information. At the time of the authority application, details (result and date of result) of the following</p>	

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			monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10 ⁹ /L) (iii) White Cell Count (x10 ⁹ /L) (iv) Reticulocytes (x10 ⁹ /L) (v) Neutrophils (x10 ⁹ /L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)	
	C14750		Atypical haemolytic uraemic syndrome (aHUS) Recommencement - Balance of Supply Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; AND Patient must not receive more than 20 weeks supply under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.	Compliance with Written Authority Required procedures
	C14753		Atypical haemolytic uraemic syndrome (aHUS) Switch from PBS-subsidised ravulizumab (all phases) - loading dose Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather	Compliance with Written Authority Required procedures

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			<p>(transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition; AND Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND AND Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. The application must indicate the most recent treatment phase that the patient is switching from. For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include all of the following: (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted.</p>	
	C14754		<p>Atypical haemolytic uraemic syndrome (aHUS) Continuing treatment Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; AND Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; OR</p>	Compliance with Written Authority Required procedures

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			<p>Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following:</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is:</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p>	

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			<p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(7) An inclusion of the individual consequences of recurrent disease, if applicable;</p> <p>(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p> <p>(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;</p> <p>(10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.</p>	
	C14781		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Initial treatment</p> <p>Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND</p> <p>Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L; AND</p> <p>Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days; AND</p> <p>Patient must have clinical features of active organ damage or impairment; AND</p> <p>Patient must not receive more than 4 weeks of treatment under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>Evidence of active and progressing TMA is defined by the following:</p>	Compliance with Written Authority Required procedures

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			<p>(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; OR (2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy consistent with aHUS; (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include all of the following: (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A detailed cover letter from the prescriber; (4) A measurement of body weight at the time of application;</p>	

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			<p>(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;</p> <p>(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply;</p> <p>(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;</p> <p>(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;</p> <p>(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.</p>	
	C14792		<p>Atypical haemolytic uraemic syndrome (aHUS) Initial treatment - Balance of Supply Patient must have received PBS-subsidised initial supply of eculizumab for this condition; AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND Patient must not receive more than 20 weeks supply under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion, and must have been submitted to Services Australia within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.</p>	Compliance with Written Authority Required procedures

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			Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.	
	C14793		<p>Atypical haemolytic uraemic syndrome (aHUS) Continuing recommencement of treatment Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition; AND Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant</p>	Compliance with Written Authority Required procedures

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			<p>resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable;</p> <p>(7) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(8) An inclusion of the individual consequences of recurrent disease, if applicable;</p> <p>(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p> <p>(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;</p> <p>(11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.</p>	
	C14799		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Recommencement of treatment</p> <p>Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; OR</p> <p>Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the</p>	Compliance with Written Authority Required procedures

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			<p>recommencement treatment phase for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10⁹/L); OR (iii) TMA-related organ impairment including on recent biopsy; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>treatment).</p> <p>The authority application must be in writing and must include all of the following:</p> <ol style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS if applicable; (6) A history of multiple episodes of aHUS following the treatment break, if applicable; (7) A history of kidney transplant if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy; (10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. 	
	C14805		<p>Atypical haemolytic uraemic syndrome (aHUS) Extended Continuing treatment Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; OR Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition; AND Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction</p>	Compliance with Written Authority Required procedures

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			<p>< 40% on current objective measurement; OR Patient must have severe TMA-related neurological impairment; OR Patient must have severe TMA-related gastrointestinal impairment; OR Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving</p>	

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			<p>treatment).</p> <p>The authority application must be in writing and must include all of the following:</p> <ol style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; (7) A history of kidney transplant, if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; (10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application; (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.</p>	
Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	C13932		<p>Cystic fibrosis</p> <p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must have at least one F508del mutation in the cystic fibrosis transmembrane</p>	Compliance with Written Authority Required procedures

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			<p>conductance (CFTR) gene; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug. Patient must be aged between 6 and 11 years inclusive. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C13962		<p>Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug. Patient must be at least 6 years of age. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p>	Compliance with Written Authority Required procedures

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			(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.	
	C13980		<p>Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be at least 6 years of age. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Written Authority Required procedures
	C13991		<p>Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged between 6 and 11 years inclusive. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Written Authority Required procedures

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Eltrombopag	C13327		Severe thrombocytopenia Second or Subsequent Continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction; AND Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.	Compliance with Authority Required procedures
	C14126		Severe thrombocytopenia Initial treatment - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details of a platelet count supporting the diagnosis of ITP. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C14127		<p>Severe thrombocytopenia Balance of supply or change of therapy The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition; AND The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction. Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.</p>	Compliance with Authority Required procedures
	C14129		<p>Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment. The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the</p>	Compliance with Authority Required procedures

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			patient's medical records.	
	C15173		Severe aplastic anaemia Continuing treatment - Second line treatment The condition must be severe aplastic anaemia; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; AND Patient must have demonstrated a response to PBS-subsidised treatment with this drug. Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records. Once platelet count is greater than 50 x 10 ⁹ /L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10 ⁹ /L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information. For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.	Compliance with Authority Required procedures
	C15174		Severe aplastic anaemia Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - First line treatment Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND The condition must be severe aplastic anaemia; AND Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment; AND The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin; AND Patient must be considered ineligible for haemopoietic stem cell transplant; AND Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). A patient may qualify for PBS-subsidised treatment under this restriction once only.	Compliance with Authority Required procedures
	C15191		Severe aplastic anaemia First line treatment	Compliance with Authority Required

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			The condition must be severe aplastic anaemia; AND Patient must not have received treatment with immunosuppressive therapy for this condition; AND The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin; AND Patient must be considered ineligible for haemopoietic stem cell transplant; AND Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	procedures
	C15192		Severe aplastic anaemia Initial treatment - Second line treatment The condition must be severe aplastic anaemia; AND Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include: (a) prior immunosuppressive therapy, including dates of treatment. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
Emtricitabine with rilpivirine with tenofovir alafenamide	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Emtricitabine with tenofovir	C4454		HIV infection	Compliance with

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alafenamide			Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Authority Required procedures - Streamlined Authority Code 4454
	C4512		Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Entecavir	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Authority Required procedures - Streamlined Authority Code 4993
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5036
	C5037		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have failed lamivudine, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5037
	C5044		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have failed lamivudine, AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR	Compliance with Authority Required procedures - Streamlined Authority Code 5044

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			Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	
Epoetin Alfa	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Epoetin Beta	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Epoetin lambda	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Epoprostenol	C13491		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND	Compliance with Authority Required procedures

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			<p>The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13505		<p>Pulmonary arterial hypertension (PAH) Initial 3 - changing to this drug in combination therapy (dual or triple therapy) The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
	C13506		<p>Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one</p>	Compliance with Authority Required procedures

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			<p>phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	
	C13510		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery</p>	Compliance with Written Authority Required procedures

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			<p>wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is: - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current. (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application.</p>	
	C13512		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>	Compliance with Written Authority Required procedures

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			<p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document</p>	

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			<p>that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13577		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C13634		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
Etanercept	C9417		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply</p> <p>Must be treated by a paediatric rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available</p>	Compliance with Authority Required procedures

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			under the above restrictions.	
	C14068		<p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment</p>	Compliance with Authority Required procedures

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			<p>cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14070		<p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated</p>	Compliance with Authority Required procedures

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			<p>according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C14071		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)</p>	<p>Compliance with Authority Required procedures</p>

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			<p>Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) the date of the last continuing prescription. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these</p>	

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			<p>timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C14154		<p>Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14154

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14155		<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14155

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			<p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
Etravirine	C5014		<p>HIV infection</p> <p>The treatment must be in addition to optimised background therapy, AND</p> <p>The treatment must be in combination with other antiretroviral agents, AND</p> <p>Patient must be antiretroviral experienced, AND</p> <p>Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.</p> <p>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5014
Everolimus	C5554		<p>Management of cardiac allograft rejection</p> <p>Management (initiation, stabilisation and review of therapy)</p> <p>Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND</p> <p>The treatment must be under the supervision and direction of a transplant unit.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5554
	C5795		<p>Management of renal allograft rejection</p> <p>Management (initiation, stabilisation and review of therapy)</p> <p>Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND</p> <p>The treatment must be under the supervision and direction of a transplant unit.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5795

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C9691		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9691
	C9693		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9693
Filgrastim	C6621		Severe chronic neutropenia Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR Patient must have neutrophil dysfunction; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 6621
	C6640		Chronic cyclical neutropenia Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 6640
	C6653		Mobilisation of peripheral blood progenitor cells The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6653
	C6654		Mobilisation of peripheral blood progenitor cells The treatment must be in a normal volunteer for use in allogeneic transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 6654

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	C6655		Assisting autologous peripheral blood progenitor cell transplantation The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 6655
	C6679		Assisting bone marrow transplantation Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 6679
	C6680		Severe congenital neutropenia Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.	Compliance with Authority Required procedures - Streamlined Authority Code 6680
	C7822		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7843		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7843
	C8667		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 8667

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	C8668		Mobilisation of peripheral blood progenitor cells The treatment must be in a normal volunteer for use in allogeneic transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 8668
	C8669		Severe congenital neutropenia Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.	Compliance with Authority Required procedures - Streamlined Authority Code 8669
	C8670		Severe chronic neutropenia Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR Patient must have neutrophil dysfunction; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 8670
	C8671		Assisting bone marrow transplantation Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 8671
	C8672		Mobilisation of peripheral blood progenitor cells The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 8672
	C8673		Chronic cyclical neutropenia Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 8673

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	C8674		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 8674
	C8696		Assisting autologous peripheral blood progenitor cell transplantation The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 8696
Ganciclovir	C4972		Cytomegalovirus disease Prophylaxis Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 4972
	C4999		Cytomegalovirus disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 4999
	C5000		Cytomegalovirus retinitis Patient must be severely immunocompromised, including due to HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 5000
	C9404		Cytomegalovirus disease Prophylaxis Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9404
	C9526		Cytomegalovirus disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9526
Glecaprevir with pibrentasvir	C7593	P7593	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 8 weeks.	
	C7615	P7615	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures
	C10268	P10268	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 16 weeks. The application must include details of the prior treatment regimen containing an NS5A inhibitor.	Compliance with Authority Required procedures
Iloprost	C13491		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to	Compliance with Authority Required procedures

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			<p>the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13505		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
	C13506		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			application to be completed by the physician with expertise in PAH.	
	C13510		<p>Pulmonary arterial hypertension (PAH) Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in</p>	Compliance with Written Authority Required procedures

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			<p>descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p>	
	C13577		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C13631		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p>	Compliance with Written Authority Required procedures

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			<p>- ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s: (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current. (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13634		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.	
Infliximab	C4524		<p>Acute severe ulcerative colitis Must be treated by a gastroenterologist; OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology]. Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital. Patient must be 6 years of age or older. For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where: (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood. For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours. At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4524

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			medical records.	
	C7777		<p>Complex refractory Fistulising Crohn disease</p> <p>Balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).</p>	Compliance with Authority Required procedures
	C8296		<p>Severe chronic plaque psoriasis</p> <p>Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply</p> <p>Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist.	
	C8844		Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 8844
	C8881		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older.	Compliance with Written Authority Required procedures

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			<p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.</p> <p>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			the first application under a new cycle under the Initial 3 treatment restriction.	
	C8883		<p>Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Written Authority Required procedures

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			<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C8940		<p>Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition</p>	Compliance with Authority Required procedures - Streamlined Authority Code 8940

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			within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8941		<p>Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The most recent PASI assessment must be no more than 1 month old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of</p>	Compliance with Written Authority Required procedures

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			<p>treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C8962		<p>Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C9065		<p>Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. At the time of the authority application, medical practitioners should request the appropriate</p>	Compliance with Written Authority Required procedures

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			<p>quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C9067		<p>Severe psoriatic arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as:</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and</p> <p>either of the following:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.</p> <p>Up to a maximum of 2 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse</p>	

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			reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9068		Severe psoriatic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C9111		Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C9188		Severe psoriatic arthritis	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	<p>Authority Required procedures - Streamlined Authority Code 9188</p>

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	C9472		<p>Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9472</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C9559		<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p> <p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Authority Required procedures
	C9584		<p>Severe chronic plaque psoriasis</p> <p>Subsequent continuing treatment, Face, hand, foot</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9584

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			<p>medical notes.</p> <p>Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C9602		<p>Severe chronic plaque psoriasis</p> <p>Subsequent continuing treatment, Whole body</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as:</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9602

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C9632		<p>Acute severe ulcerative colitis Must be treated by a gastroenterologist; OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology]. Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital. Patient must be 6 years of age or older. For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where: (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood. For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours. At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9632
	C9668		Moderate to severe Crohn disease	Compliance with

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			<p>Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 30 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. The PCDAI assessment must be no more than 1 month old at the time of prescribing. The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	<p>Authority Required procedures - Streamlined Authority Code 9668</p>
	C9669		<p>Moderate to severe Crohn disease Balance of supply for paediatric patient Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p>	<p>Compliance with Authority Required procedures</p>

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			<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.</p>	
	C9677		<p>Complex refractory Fistulising Crohn disease Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in</p>	Compliance with Written Authority Required procedures

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			<p>the necessity for permanent withdrawal of treatment.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p>	
	C9719		<p>Moderate to severe Crohn disease</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND</p> <p>Patient must have a total PCDAI score of 30 points or less; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.</p> <p>The PCDAI assessment must be no more than 1 month old at the time of application.</p> <p>Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C9721		<p>Moderate to severe Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 30 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition. The PCDAI assessment must be no more than 1 month old at the time of application. The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious</p>	Compliance with Written Authority Required procedures

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			<p>adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C9732		<p>Complex refractory Fistulising Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9732
	C9751		<p>Moderate to severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting</p>	

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			<p>of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C9754		<p>Moderate to severe ulcerative colitis</p> <p>Balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.	
	C9775		Moderate to severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 30 points or less; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 6 to 17 years inclusive. The PCDAI assessment must be no more than 1 month old at the time of prescribing. The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.	Compliance with Authority Required procedures - Streamlined Authority Code 9775
	C9779		Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks);	Compliance with Authority Required procedures

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			<p>OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.</p>	
	C9783		<p>Complex refractory Fistulising Crohn disease</p> <p>First continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug.</p> <p>An adequate response is defined as:</p> <p>(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or</p> <p>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.</p> <p>The most recent fistula assessment must be no more than 1 month old at the time of application.</p> <p>The application for first continuing treatment with this drug must include an assessment of the</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum of 24 weeks of treatment with this drug will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p>	
	C9787		<p>Complex refractory Fistulising Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9787
	C9803		Complex refractory Fistulising Crohn disease	Compliance with Written

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			<p>Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 1 month old at the time of application. Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time</p>	Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C11158		Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C12003		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)	Compliance with Written Authority Required procedures

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			<p>Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years. Patient must be 6 years of age or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12025		<p>Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological</p>	Compliance with Written Authority Required procedures

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			<p>medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of the most recent clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of</p>	

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			<p>treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C12042		<p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR</p> <p>Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.</p> <p>Patient must be 6 years of age or older.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12042

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			<p>Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12043		<p>Severe Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or</p> <p>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and</p> <p>(iii) the date of clinical assessment.</p> <p>All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p>	

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			If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.	
	C12049		<p>Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years). Patient must be 6 years of age or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.</p> <p>Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.</p> <p>A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Details of the accepted toxicities including severity can be found on the Services Australia website. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C12051		<p>Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12051

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C12059		<p>Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12063		<p>Severe Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must be aged 18 years or older.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or</p> <p>(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and</p> <p>(iii) the date of clinical assessment; and</p> <p>(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C12069		<p>Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12069

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C12074		<p>Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12074

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12313		<p>Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR</p> <p>Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.</p> <p>Patient must be 6 years of age or older.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.</p> <p>An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.</p> <p>A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
	C13518		<p>Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C13526		<p>Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be at least 18 years of age. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>Applications for authorisation must be made in writing and must include:</p> <ul style="list-style-type: none"> (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: <ul style="list-style-type: none"> (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:</p> <ul style="list-style-type: none"> (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. <p>Evidence of intestinal inflammation includes:</p> <ul style="list-style-type: none"> (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. <p>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time</p>	

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			<p>of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C13584		<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved</p>	

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Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C13586		<p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
	C13587		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

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Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
	C13639		<p>Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR</p> <p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have evidence of intestinal inflammation; OR</p> <p>Patient must be assessed clinically as being in a high faecal output state; OR</p> <p>Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iii) the date of the most recent clinical assessment.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C13640		<p>Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>drug for this condition during the current treatment cycle; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p>	

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			<p>This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C13641		<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have an externally draining enterocutaneous or rectovaginal fistula.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.</p> <p>The most recent fistula assessment must be no more than 1 month old at the time of application.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C13691		<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Must be treated by a paediatrician; OR</p> <p>Must be treated by a specialist paediatric gastroenterologist.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one</p>	Compliance with Authority Required procedures

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			<p>month old at the time of application.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C13692		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as:</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C13702		<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p>	Compliance with Written Authority Required procedures

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			<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition. The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
	C13719		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a dermatologist.</p>	Compliance with Written Authority Required procedures

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			<p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <ul style="list-style-type: none"> (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: <ul style="list-style-type: none"> (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition</p>	

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			within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C14359		<p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of</p>	Compliance with Written Authority Required procedures

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			<p>a hand or sole of a foot where:</p> <ul style="list-style-type: none"> (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: <ul style="list-style-type: none"> (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C14360		<p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p>	Compliance with Written Authority Required procedures

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			<p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
	C14502		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p>	

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			<p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p>	

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			<p>(a) the active joint count, ESR and/or CRP result and date of results;</p> <p>(b) details of prior treatment, including dose and date/duration of treatment.</p> <p>(c) If applicable, details of any contraindications/intolerances.</p> <p>(d) If applicable, the maximum tolerated dose of methotrexate.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14504		<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14504

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			<p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	
	C14505		<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14505</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	
	C14507		<p>Severe active rheumatoid arthritis First continuing treatment - balance of supply</p>	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	procedures
	C14544		<p>Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the active joint count, ESR and/or CRP result and date of result;</p> <p>(b) the most recent biological agent and the date of the last continuing prescription.</p> <p>(c) If applicable, the new baseline scores.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14546		<p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

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			<p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14547		<p>Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14548		<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment; AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.</p>	
	C14585		<p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14585

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	
	C14597		<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Written Authority Required procedures

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			<p>An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C14615		<p>Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive</p>	Compliance with Written Authority Required procedures

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			<p>movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
	C14623		Severe active rheumatoid arthritis	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records.</p>	Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
	C14638		<p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14638</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			records.	
	C14667		<p>Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a baseline ESR and/or CRP level.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C14683		<p>Ankylosing spondylitis</p> <p>First continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14683

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			<p>(a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14689		<p>Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14689

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14701		<p>Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14701

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			the first application under a new cycle under the Initial 3 treatment restriction.	
	C14705		<p>Ankylosing spondylitis</p> <p>Continuing treatment - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Authority Required procedures
	C14707		<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 18 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14716		<p>Ankylosing spondylitis</p> <p>First continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14718		<p>Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialed, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:</p> <ul style="list-style-type: none"> (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. <p>The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the 	

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			<p>latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C14723		<p>Ankylosing spondylitis</p> <p>Subsequent continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14723

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14724		<p>Ankylosing spondylitis Subsequent continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age.</p> <p>Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14737		<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 18 weeks of treatment under this restriction.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must be at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be</p>	

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			<p>deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
Interferon Gamma-1b	C6222		<p>Chronic granulomatous disease</p> <p>Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6222
	C9639		<p>Chronic granulomatous disease</p> <p>Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9639
Ivacaftor	C15251		<p>Cystic fibrosis</p> <p>Initial treatment - New patient (gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR</p> <p>Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (i) the specific CFTR mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C15252		<p>Cystic fibrosis</p> <p>Continuing treatment (gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction per authority application; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors:</p>	Compliance with Written Authority Required procedures

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			<p>boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C15253		<p>Cystic fibrosis</p> <p>Initial treatment - New patient (non-gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data; AND</p> <p>Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA approved Product Information. Quote each of the: (i) the specific mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C15255		<p>Cystic fibrosis</p> <p>Continuing treatment (non-gating mutations)</p> <p>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND</p> <p>Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must not receive more than 24 weeks of treatment under this restriction per authority application; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be aged 4 months or older.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.</p> <p>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.</p> <p>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.</p> <p>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
Lamivudine	C4454		<p>HIV infection</p> <p>Continuing</p> <p>Patient must have previously received PBS-subsidised therapy for HIV infection; AND</p> <p>The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		<p>HIV infection</p> <p>Initial</p> <p>Patient must be antiretroviral treatment naïve; AND</p> <p>The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4512

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Authority Required procedures - Streamlined Authority Code 4993
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5036
Lamivudine with zidovudine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Lanreotide	C4575		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Authority Required procedures - Streamlined Authority Code 4575
	C7025		Acromegaly The condition must be active; AND	Compliance with Authority Required

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			<p>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND</p> <p>The treatment must be after failure of other therapy including dopamine agonists; OR</p> <p>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR</p> <p>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.</p> <p>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</p>	procedures - Streamlined Authority Code 7025
	C7509		<p>Functional carcinoid tumour</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must be causing intractable symptoms; AND</p> <p>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND</p> <p>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND</p> <p>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7509
	C7532		<p>Acromegaly</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must be active; AND</p> <p>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND</p> <p>The treatment must be after failure of other therapy including dopamine agonists; OR</p> <p>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7532

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.</p> <p>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</p>	
	C9260		<p>Functional carcinoid tumour</p> <p>The condition must be causing intractable symptoms; AND</p> <p>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND</p> <p>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND</p> <p>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9260
	C9261		<p>Acromegaly</p> <p>The condition must be active; AND</p> <p>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND</p> <p>The treatment must be after failure of other therapy including dopamine agonists; OR</p> <p>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR</p> <p>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.</p> <p>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9261

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	C10061		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10061
	C10075		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10075
	C10077		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10077
Lanthanum	C5530		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR	Compliance with Authority Required procedures - Streamlined Authority Code 5530

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	
	C9762		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9762
Lenalidomide	C13782		Relapsed and/or refractory multiple myeloma Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS; AND Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.	Compliance with Authority Required procedures
	C13785		Multiple myeloma Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND Patient must not have been treated with lenalidomide or bortezomib for this condition; AND The treatment must not exceed a total of 4 cycles under this restriction. The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and	Compliance with Written Authority Required procedures

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			<p>(2) nomination of which disease activity parameters will be used to assess response. To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13786		<p>Multiple myeloma Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND Patient must not have been treated with lenalidomide or bortezomib for this condition; AND The treatment must not exceed a total of 4 cycles under this restriction. The authority application must be made via the online PBS Authorities System (real time</p>	Compliance with Written Authority Required procedures

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			<p>assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and</p> <p>(2) nomination of which disease activity parameters will be used to assess response.</p> <p>To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13787		<p>Multiple myeloma</p> <p>Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p> <p>AND</p>	Compliance with Authority Required procedures

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			<p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
	C13791		<p>Multiple myeloma</p> <p>Initial treatment with lenalidomide monotherapy in newly diagnosed disease</p> <p>The treatment must be as monotherapy; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma; AND</p> <p>Patient must not have progressive disease following autologous stem cell transplant (ASCT).</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and</p> <p>(2) the date the autologous stem cell transplant was performed; and</p> <p>(3) nomination of which disease activity parameters will be used to assess progression.</p> <p>To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or,</p>	Compliance with Written Authority Required procedures

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			<p>confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13801		<p>Myelodysplastic syndrome</p> <p>Continuing treatment</p> <p>Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome; AND</p> <p>Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide; AND</p> <p>Patient must not have progressive disease; AND</p> <p>The condition must not have progressed to acute myeloid leukaemia.</p> <p>The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.</p>	Compliance with Written Authority Required procedures

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			<p>The following evidence of response must be provided at each application:</p> <ul style="list-style-type: none"> (i) a haemoglobin level taken within the last 4 weeks; and (ii) the date of the last transfusion; and (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; <p>All reports must be documented in the patient's medical records. For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:</p> <ul style="list-style-type: none"> (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). 	
	C13803		<p>Multiple myeloma Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease The condition must be confirmed by a histological diagnosis; AND The treatment must be as monotherapy; OR The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must have undergone or be ineligible for a primary stem cell transplant. Progressive disease is defined as at least 1 of the following:</p> <ul style="list-style-type: none"> (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10</p>	Compliance with Written Authority Required procedures

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			<p>g per L serum M protein.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and</p> <p>(2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and</p> <p>(3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and</p> <p>(4) details of the basis of the diagnosis of progressive disease or failure to respond; and</p> <p>(5) nomination of which disease activity parameters will be used to assess response.</p> <p>To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13804		<p>Multiple myeloma</p> <p>Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide</p>	Compliance with Authority Required

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			<p>therapy in newly diagnosed disease Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be as monotherapy. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	procedures
	C13805		<p>Multiple myeloma Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma; AND The treatment must be as monotherapy; OR The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.</p>	Compliance with Authority Required procedures
	C13810		<p>Myelodysplastic syndrome Initial treatment The treatment must be limited to a maximum duration of 16 weeks; AND Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic</p>	Compliance with Written Authority Required procedures

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			<p>Scoring System (IPSS); AND Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND Patient must be red blood cell transfusion dependent. Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias. Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:</p> <ol style="list-style-type: none"> 1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR 2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR 5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias. <p>Classification of a patient as red blood cell transfusion dependent requires that:</p> <ol style="list-style-type: none"> (i) the patient has been transfused within the last 8 weeks; and (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment. <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <ol style="list-style-type: none"> (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and 	

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			<p>(c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and</p> <p>(d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.</p> <p>All the reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13811		<p>Multiple myeloma</p> <p>Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)</p> <p>Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND</p> <p>The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p> <p>The treatment must not exceed a total of 4 cycles under this restriction.</p>	Compliance with Authority Required procedures
	C13812		<p>Multiple myeloma</p> <p>Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation</p> <p>The condition must be newly diagnosed; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be ineligible for a primary stem cell transplantation; AND</p> <p>The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and</p> <p>(2) confirmation of ineligibility for prior stem cell transplant; and</p> <p>(3) nomination of which disease activity parameters will be used to assess response.</p>	Compliance with Written Authority Required procedures

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			<p>To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13813		<p>Multiple myeloma Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles) Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND The treatment must not exceed a total of 2 cycles under this restriction.</p>	Compliance with Authority Required procedures
	C14362		<p>Relapsed and/or refractory multiple myeloma Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone</p>	Compliance with Authority Required

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			Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS; AND Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.	procedures
Levodopa with carbidopa	C10138	P10138	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic.	Compliance with Authority Required procedures - Streamlined Authority Code 10138
	C10161	P10161	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic.	Compliance with Authority Required procedures - Streamlined Authority Code 10161
	C10363	P10363	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 10363
	C10375	P10375	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 10375
Lipegfilgrastim	C7822		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7843		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial	Compliance with Authority Required

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			remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	procedures - Streamlined Authority Code 7843
	C9224		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 9224
	C9322		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 9322
Lopinavir with ritonavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Lumacaftor with ivacaftor	C14757		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Written Authority Required procedures

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			<p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p> <p>Patient must be 1 year of age or older.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C14765		<p>Cystic fibrosis</p> <p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.</p> <p>Patient must be 1 year of age or older.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Written Authority Required procedures
	C14783		<p>Cystic fibrosis</p> <p>Initial treatment</p>	Compliance with Written Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.</p> <p>Patient must be aged between 6 and 11 years inclusive.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	procedures
	C14784		<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition.</p>	Compliance with Written Authority Required procedures

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			<p>Patient must be aged between 6 and 11 years inclusive.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C14785		<p>Cystic fibrosis Continuing treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.</p> <p>Patient must be 12 years of age or older.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Written Authority Required procedures
	C14796		<p>Cystic fibrosis Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition. Patient must be 12 years of age or older. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
Macitentan	C11229		<p>Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'). Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung</p>	Compliance with Authority Required procedures

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			<p>disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or</p> <p>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13496		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p>	
	C13497		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin</p>	Compliance with Authority Required procedures

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			<p>receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.</p>	
	C13499		<p>Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.</p>	Compliance with Authority Required procedures
	C13500		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease,</p>	

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			where the total lung capacity is less than 70% of predicted. The test results must not be more than 6 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C13575		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C13576		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to	Compliance with Authority Required procedures

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			<p>the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13582		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
Mannitol	C7362		<p>Cystic fibrosis The treatment must be as monotherapy; AND Patient must be intolerant or inadequately responsive to dornase alfa. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7362

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			<p>negative result.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</p> <p>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.</p> <p>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:</p> <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.</p>	
	C7367		<p>Cystic fibrosis</p> <p>The treatment must be in combination with dornase alfa; AND</p> <p>Patient must be inadequately responsive to dornase alfa; AND</p> <p>Patient must have trialled hypertonic saline for this condition.</p> <p>Patient must be 6 years of age or older.</p> <p>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</p> <p>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.</p> <p>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:</p> <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7367

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			with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	
	C9527		<p>Cystic fibrosis The treatment must be as monotherapy; AND Patient must be intolerant or inadequately responsive to dornase alfa. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9527
	C9593		<p>Cystic fibrosis The treatment must be in combination with dornase alfa; AND Patient must be inadequately responsive to dornase alfa; AND Patient must have trialled hypertonic saline for this condition. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9593

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			(FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	
Maraviroc	C5008		HIV infection Patient must be infected with CCR5-tropic HIV-1, AND The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.	Compliance with Authority Required procedures - Streamlined Authority Code 5008
Mepolizumab	C13865		Chronic rhinosinusitis with nasal polyps (CRSwNP) Continuing treatment Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			authority application. Patient must be at least 18 years of age.	
	C13890		<p>Chronic rhinosinusitis with nasal polyps (CRSwNP) Initial treatment Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP. Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; OR Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types; AND Patient must have undergone surgery for the removal of nasal polyps; OR Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery; AND Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10); AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma; AND Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented; AND Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months. Patient must be at least 18 years of age. Optimised nasal polyp therapy includes: (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated</p>	Compliance with Written Authority Required procedures

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			<p>(b) if required, nasal irrigation with saline</p> <p>Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form,</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),</p> <p>(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,</p> <p>(d) details (date and treatment) of nasal polyp surgery; or</p> <p>(e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,</p> <p>(f) the eosinophil count and date,</p> <p>(g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.</p>	
	C15344		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). 	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (date and duration of treatment) of prior biological medicine treatment; and</p> <p>(c) eosinophil count and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C15353		<p>Uncontrolled severe asthma Continuing treatment</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 12 years or older.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.</p> <p>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.</p> <p>The authority application must be made in writing and must include:</p> <ol style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <ol style="list-style-type: none"> (a) if applicable, details of maintenance oral corticosteroid dose; and (b) a completed Asthma Control Questionnaire (ACQ-5) score. 	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C15376		<p>Uncontrolled severe asthma</p> <p>Balance of supply</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR</p> <p>The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.</p>	Compliance with Authority Required procedures
	C15400		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and</p> <p>(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and</p> <p>(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(d) the eosinophil count and date; and</p> <p>(e) Asthma Control Questionnaire (ACQ-5) score.</p>	
Methadone	C15358		<p>Opioid dependence</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p> <p>A medical practitioner must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15358
Methoxsalen	C10971	P10971	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Initial treatment	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR</p> <p>Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR</p> <p>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND</p> <p>Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a medical physician working under the supervision of a haematologist.</p> <p>Patient must be aged 18 years or over.</p>	procedures - Streamlined Authority Code 10971
	C10985	P10985	<p>Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma</p> <p>Initial treatment</p> <p>Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR</p> <p>Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR</p> <p>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND</p> <p>Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a medical physician working under the supervision of a haematologist.</p> <p>Patient must be aged 18 years or over.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10985
	C10988	P10988	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment</p>	<p>Authority Required procedures - Streamlined Authority Code 10988</p>
	C10989	P10989	<p>Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50%</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 10989</p>

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment	
	C12531	P12531	<p>Chronic graft versus host disease Continuing treatment Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment; AND Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode. Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12531
	C12546	P12546	<p>Chronic graft versus host disease Initial treatment in a treatment episode The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; OR The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; OR The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed. Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25th dose) of a treatment episode; AND Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12546

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition.	
	C12567	P12567	Chronic graft versus host disease Continuing treatment Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment; AND Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode. Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse.	Compliance with Authority Required procedures - Streamlined Authority Code 12567
	C12579	P12579	Chronic graft versus host disease Initial treatment in a treatment episode The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; OR The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; OR The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed. Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25th dose) of a treatment episode; AND Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR	Compliance with Authority Required procedures - Streamlined Authority Code 12579

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition.	
Methoxy polyethylene glycol-epoetin beta	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Midostaurin	C11699		Acute Myeloid Leukaemia Maintenance therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not be undergoing or have undergone a stem cell transplant. A maximum of 9 cycles will be authorised under this restriction in a lifetime. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	
	C13001		<p>Acute Myeloid Leukaemia Induction / Consolidation therapy Patient must not have received prior chemotherapy as induction therapy for this condition; OR The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy and the patient must not have progressive disease; AND The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority; AND The condition must not be acute promyelocytic leukaemia; AND The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition. A maximum of 6 cycles will be authorised under this restriction in a lifetime. Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline. The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p>	Compliance with Authority Required procedures
	C13013		Acute Myeloid Leukaemia	Compliance with Written

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			<p>Maintenance therapy - Initial treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin confirmed through a bone marrow biopsy pathology report; AND Patient must not be undergoing or have undergone a stem cell transplant; AND The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority. A maximum of 3 cycles will be authorised under this restriction in a lifetime. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and (b) confirmation that the patient does not have progressive disease; and (c) details (date, unique identifying number/code or provider number) of a recent bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient is in complete remission; and</p>	Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			(d) details (date, unique identifying number/code or provider number) of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin. All reports must be documented in the patient's medical records. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
Mycophenolic Acid	C4084		Prophylaxis of renal allograft rejection Management The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required Procedures – Streamlined Authority Code 4084
	C4095		WHO Class III, IV or V lupus nephritis Management The condition must be proven by biopsy, Must be treated by a nephrologist or in consultation with a nephrologist. The name of the consulting nephrologist must be included in the patient medical records.	Compliance with Authority Required Procedures – Streamlined Authority Code 4095
	C5554		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5554
	C5600		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5600
	C5653		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5653
	C5795		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND	Compliance with Authority Required procedures - Streamlined

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			The treatment must be under the supervision and direction of a transplant unit.	Authority Code 5795
	C9689		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9689
	C9690		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9690
	C9691		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9691
	C9692		Prophylaxis of renal allograft rejection Management The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9692
	C9693		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9693
	C9809		WHO Class III, IV or V lupus nephritis Management The condition must be proven by biopsy. Must be treated by a nephrologist or in consultation with a nephrologist. The name of the consulting nephrologist must be included in the patient medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9809
Natalizumab	C13625		Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist. The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a	Compliance with Authority Required procedures - Streamlined Authority Code 13625

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.</p>	
	C13718		<p>Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist. The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13718

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Nevirapine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
	C4526		HIV infection Initial Patient must have been stabilised on nevirapine immediate release; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4526
Nivolumab with relatlimab	C14812	P14812	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be uveal melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must weigh 40 kg or more; AND Patient must be at least 12 years of age. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 14812

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C14815	P14815	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 14815
	C14819	P14819	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be uveal melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must weigh 40 kg or more; AND Patient must be at least 12 years of age. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 14819
	C14829	P14829	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 14829
Nusinersen	C12672		Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)	Compliance with Written

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			<p>Initial treatment - Loading doses Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA. The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND Patient must be untreated with gene therapy. Patient must be 18 years of age or under. Defined signs and symptoms of type I SMA are: i) Onset before 6 months of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type II SMA are: i) Onset between 6 and 18 months; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Weakness in trunk righting/derotation; or v) Hypotonia; or</p>	<p>Authority Required procedures</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			vi) Absence of deep tendon reflexes; or vii) Failure to gain weight appropriate for age; or viii) Any active chronic neurogenic changes; or ix) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type IIIa SMA are: i) Onset between 18 months and 3 years of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Application for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following: i) specification of SMA type (I, II or IIIa); and (ii) sign(s) and symptom(s) that the patient has experienced; and (iii) patient's age at the onset of sign(s) and symptom(s).	
	C12676		Spinal muscular atrophy (SMA) Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with one of: (i) Type 1 SMA, or, (ii) pre-symptomatic SMA Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples); AND The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition.	Compliance with Written Authority Required procedures

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			<p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.</p> <p>Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy; OR</p> <p>Patient must have a prior authority approval for any drug PBS-listed for pre-symptomatic SMA, with at least one approval having been for gene therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA. Confirm that a previous PBS authority application has been approved for one of the following:</p> <p>(i) Symptomatic Type 1 SMA; or</p> <p>(ii) Pre-symptomatic SMA treated with nusinersen.</p> <p>Definition:</p> <p>Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.</p> <p>0. Absence of developmental states (1 to 9) listed below:</p> <p>1. Rolls from side to side on back;</p> <p>2. Child holds head erect for at least 3 seconds unsupported;</p> <p>3. Sitting, but with assistance;</p> <p>4. Sitting without assistance:</p> <p>(a) Child sits up straight with the head erect for at least 10 seconds;</p> <p>(b) Child does not use arms or hands to balance body or support position.</p> <p>5. Hands and knees crawling:</p> <p>(a) Child alternately moves forward or backwards on hands and knees;</p> <p>(b) The stomach does not touch the supporting surface;</p> <p>(c) There are continuous and consecutive movements at least 3 in a row.</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>6. Standing with assistance: (a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object; (b) The body does not touch the stable object, and the legs support most of the body weight; (c) Child thus stands with assistance for at least 10 seconds.</p> <p>7. Standing alone: (a) Child stands in upright position on both feet (not on the toes) with the back straight; (b) The leg supports 100% of the child's weight; (c) There is no contact with a person or object; (d) Child stands alone for at least 10 seconds.</p> <p>8. Walking with assistance: (a) Child is in an upright position with the back straight; (b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands; (c) One leg moves forward while the other supports part of the body weight; (d) Child takes at least 5 steps in this manner.</p> <p>9. Walking alone: (a) Child takes at least 5 steps independently in upright position with the back straight; (b) One leg moves forward while the other supports most of the body weight; (c) There is no contact with a person or object.</p> <p>Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)). Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.</p>	
	C13222		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Initial PBS-subsidised treatment in a child The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p>	Compliance with Written Authority Required procedures

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			<p>Patient must be of an age that is prior to their 19th birthday at the time of this authority application; AND</p> <p>Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:</p> <p>(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,</p> <p>(ii) Proximal weakness,</p> <p>(iii) Hypotonia,</p> <p>(iv) Absence of deep tendon reflexes,</p> <p>(v) Any active denervation or chronic neurogenic changes found on electromyography,</p> <p>(vi) A compound muscle action potential below normative values for an age-matched child.</p> <p>In this authority application, confirm:</p> <p>(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,</p> <p>(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,</p> <p>(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.</p>	

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	C13270		<p>Spinal muscular atrophy (SMA)</p> <p>Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene;</p> <p>AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood; AND</p> <p>Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:</p> <p>(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,</p> <p>(ii) Proximal weakness,</p> <p>(iii) Hypotonia,</p> <p>(iv) Absence of deep tendon reflexes,</p>	Compliance with Written Authority Required procedures

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			(v) Failure to gain weight appropriate for age, (vi) Any active denervation or chronic neurogenic changes found on electromyography, (vii) A compound muscle action potential below normative values for an age-matched child. In this authority application, confirm: (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy, (2) which of the above (i to vii) (at least 1) were present during childhood, (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.	
	C14370		Spinal muscular atrophy (SMA) Changing the prescribed therapy Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. Patient must be untreated with gene therapy; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.	Compliance with Authority Required procedures
	C14421		Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Changing the prescribed therapy Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND	Compliance with Authority Required procedures

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			<p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Patient must be untreated with gene therapy; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p>	
	C14433		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p>	Compliance with Authority Required procedures
	C14459		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in an adult where treatment was initiated in adulthood</p> <p>The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR</p> <p>The treatment must be occurring within the first 104 weeks from the first administered dose; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.</p> <p>A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.</p> <p>PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.</p> <p>Undertake re-assessments for a clinically meaningful response at least every six months.</p> <p>Document these re-assessments in the patient's medical records.</p> <p>In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HF MSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).</p>	
	C15066		<p>Pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene;</p> <p>AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>copies of the survival motor neuron 2 (SMN2) gene; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND Patient must be untreated with gene therapy. Patient must be aged under 36 months prior to commencing treatment. Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include: (a) a completed authority prescription form; and (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following: (i) confirmation of genetic diagnosis of SMA; and (ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p>	
	C15069		<p>Spinal muscular atrophy (SMA) Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy. Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the</p>	Compliance with Authority Required procedures

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			absence of a potentially reversible cause while being treated with this drug. Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.	
	C15112		Spinal muscular atrophy (SMA) Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy. Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.	Compliance with Authority Required procedures
	C15116		Pre-symptomatic spinal muscular atrophy (SMA) Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND</p> <p>Patient must be untreated with gene therapy.</p> <p>Patient must be aged under 36 months prior to commencing treatment.</p> <p>Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:</p> <p>(i) confirmation of genetic diagnosis of SMA; and</p> <p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p>	
Ocrelizumab	C7386		<p>Multiple sclerosis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not show continuing progression of disability while on treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have demonstrated compliance with, and an ability to tolerate this therapy.</p> <p>Must be treated by a neurologist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7386
	C7699		Multiple sclerosis	Compliance with

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient;</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must be ambulatory (without assistance or support).</p> <p>Must be treated by a neurologist.</p> <p>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p>	<p>Authority Required procedures - Streamlined Authority Code 7699</p>
	C9523		<p>Multiple sclerosis</p> <p>Initial treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient;</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must be ambulatory (without assistance or support).</p> <p>Must be treated by a neurologist.</p> <p>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9523</p>
	C9635		<p>Multiple sclerosis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p> <p>AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9635</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Patient must not show continuing progression of disability while on treatment with this drug; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	
Octreotide	C5901		Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 5901
	C5906		Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 5906
	C6369		Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 6369
	C6390		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND	Compliance with Authority Required procedures - Streamlined Authority Code 6390

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			The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	
	C8161		Acromegaly The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 8161
	C8165		Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 8165
	C8197		Acromegaly Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Authority Code 8197
	C8198		Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 8198
	C8208		Functional carcinoid tumour Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 8208
	C9232		Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the	Compliance with Authority Required procedures - Streamlined Authority Code 9232

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			frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	
	C9233		Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms-3 times daily; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 9233
	C9262		Acromegaly The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 9262
	C9288		Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and	Compliance with Authority Required procedures - Streamlined Authority Code 9288

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			having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	
	C9289		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9289
	C9313		Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9313
	C10061		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10061
	C10075		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND	Compliance with Authority Required procedures - Streamlined Authority Code 10075

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			The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	
	C10077		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10077
Omalizumab	C7046		Severe chronic spontaneous urticaria Continuing treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.	Compliance with Authority Required procedures
	C7055		Severe chronic spontaneous urticaria Initial treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). The condition must be based on both physical examination and patient history (to exclude any	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>factors that may be triggering the urticaria); AND Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines; AND Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy; AND Patient must not receive more than 12 weeks of treatment under this restriction. A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following: 1) a H2 receptor antagonist (150 mg twice per day); or 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or 3) doxepin (up to 25 mg three times a day) If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include: (i) demonstration of failure to achieve an adequate response to standard therapy; and (ii) drug names and doses of standard therapies that the patient has failed; and (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.</p>	
	C15346		<p>Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p>	Compliance with Written Authority Required procedures

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			<p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND</p> <p>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND</p> <p>Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond</p>	

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			<p>to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (date and duration of treatment) of prior biological medicine treatment; and</p> <p>(c) the IgE results and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>	
	C15347		<p>Uncontrolled severe asthma</p> <p>Continuing treatment</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND</p>	Compliance with Authority Required procedures

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			<p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be aged 12 years or older.</p> <p>An adequate response to omalizumab treatment is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).</p> <p>All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.</p> <p>The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.</p> <p>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological</p>	

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			<p>medicine for severe asthma within the current treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5) score; and</p> <p>(b) If applicable, maintenance oral corticosteroid dose; and</p> <p>(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.</p>	
	C15350		<p>Uncontrolled severe allergic asthma</p> <p>Initial treatment</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p>	Compliance with Written Authority Required procedures

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			<p>Patient must be aged 6 to less than 12 years.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>Patient must be under the care of the same physician for at least 6 months.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;</p> <p>AND</p> <p>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),</p> <p>AND</p> <p>(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that</p>	

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			<p>there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and</p> <p>(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(c) the IgE result and date; and</p> <p>(d) Asthma Control Questionnaire (ACQ-5) score; or</p> <p>(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p>	
	C15352		<p>Uncontrolled severe allergic asthma</p> <p>Continuing treatment</p>	Compliance with Authority Required procedures

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			<p>Patient must have a documented history of severe allergic asthma; AND</p> <p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.</p> <p>An adequate response to omalizumab treatment is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR</p> <p>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to</p>	

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			<p>the TGA-approved Product Information), sufficient for 24 weeks of therapy.</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>	
	C15376		<p>Uncontrolled severe asthma</p> <p>Balance of supply</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR</p> <p>The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.</p>	Compliance with Authority Required procedures
	C15401		<p>Uncontrolled severe asthma</p> <p>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment</p>	Compliance with Written Authority Required procedures

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			<p>cycle following a break in PBS subsidised biological medicine therapy)</p> <p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR</p> <p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND</p> <p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in</p>	

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			<p>the patient's medical records; AND</p> <p>Patient must not receive more than 32 weeks of treatment under this restriction; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;</p> <p>AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p> <p>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND</p> <p>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment,</p>	

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			<p>should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for commencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and 	

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			(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) the IgE result and date; and (e) Asthma Control Questionnaire (ACQ-5) score.	
	C15403		Uncontrolled severe allergic asthma Balance of supply in a patient aged 6 to 12 years Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.	Compliance with Authority Required procedures
Onasemnogene abeparvovec	C12639		Spinal muscular atrophy (SMA) Use in a patient untreated with disease modifying therapies for this condition The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND Patient must have experienced at least two of the defined signs/symptoms of Type 1 SMA specified below; OR The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND The treatment must be given concomitantly with best supportive care for this condition. Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the	Compliance with Written Authority Required procedures

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			<p>management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND</p> <p>Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.</p> <p>Patient must be no older than 9 months of age; AND</p> <p>Patient must have symptomatic Type 1 SMA; OR</p> <p>Patient must have pre-symptomatic SMA.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribing Instructions:</p> <p>In the relevant PBS Authority Application form, specify the following:</p> <p>(i) the SMA type being treated: symptomatic Type 1 SMA, or, pre-symptomatic SMA;</p> <p>(ii) for Type 1 SMA, the signs/symptoms that the patient has experienced, together with the patient's age at the onset of these signs/symptoms.</p> <p>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.</p> <p>Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:</p> <p>(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.</p> <p>If the condition is pre-symptomatic SMA, confirm that there is genetic test finding that substantiates the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).</p> <p>Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.</p>	

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			<p>Defined signs and symptoms of type I SMA are:</p> <ul style="list-style-type: none"> i) Onset before 6 months of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. 	
	C14468		<p>Spinal muscular atrophy (SMA) Use in a patient untreated with disease modifying therapies for this condition The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND The treatment must be given concomitantly with best supportive care for this condition. Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.</p>	Compliance with Written Authority Required procedures

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			<p>Patient must be no older than 9 months of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.</p> <p>Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:</p> <p>(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.</p> <p>Confirm that there is a genetic test finding that substantiates the number of SMN2 gene copies to be 3 and has been determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).</p> <p>Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.</p>	
	C14469		<p>Spinal muscular atrophy (SMA)</p> <p>Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition;</p> <p>AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing;</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>AND Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased. Patient must be no older than 9 months of age; AND Patient must have symptomatic Type 1 SMA; OR Patient must have pre-symptomatic SMA. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA. Confirm that a previous PBS authority application has been approved for one of the following: (i) Symptomatic Type 1 SMA; or (ii) Pre-symptomatic SMA. State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials. Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.</p>	
Pamidronic Acid	C4433		<p>Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy</p>	Compliance with Authority Required procedures – Streamlined Authority Code 4433
	C5218		Multiple Myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5218
	C5291		<p>Bone metastases The condition must be due to breast cancer.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5291
	C9234		Hypercalcaemia of malignancy	Compliance with

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			Patient must have a malignancy refractory to anti-neoplastic therapy.	Authority Required procedures - Streamlined Authority Code 9234
	C9315		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9315
	C9335		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9335
Pasireotide	C9088		<p>Acromegaly Initial treatment Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; OR Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN); AND The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. Patient must be aged 18 years or older. If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication. If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as: 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR 2) IGF-1 level is greater than the age- and sex-adjusted ULN. In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.</p> <p>Biochemical evidence of remission is defined as:</p> <p>1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR</p> <p>2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)</p> <p>The authority application must be made in writing and must include:</p> <p>a) a completed authority prescription form; and</p> <p>b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and</p> <p>c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and</p> <p>d) a recent result of GH or IGF-1 levels must be provided.</p>	
	C9089		<p>Acromegaly</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p> <p>AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.</p> <p>Patient must be aged 18 years or older.</p> <p>In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.</p> <p>Biochemical evidence of remission is defined as:</p> <p>1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR</p> <p>2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)</p> <p>In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.</p>	Compliance with Authority Required procedures
Pegcetacoplan	C13616		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>First continuing treatment</p> <p>Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND</p> <p>The treatment must not be in combination with a Complement 5 (C5) inhibitor.</p> <p>Must be treated by a haematologist; OR</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	
	C13655		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment (new patient) Patient must not have received prior treatment with this drug for this condition; AND Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months; AND Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L; OR Patient must be intolerant to C5 inhibitors as determined by the treating physician; AND Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred; AND The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy. Must be treated by a haematologist; OR</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	
	C13710		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 3 (switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)' criteria; OR Patient must have received prior PBS-subsidised treatment with at least one C5 inhibitor and returning to pegcetacoplan treatment for reasons other than post pregnancy; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy. Must be treated by a haematologist; OR</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x109/L) (iii) White Cell Count (x109/L) (iv) Reticulocytes (x109/L) (v) Neutrophils (x109/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.</p>	
	C13743		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with a Complement 5 (C5) inhibitor. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>patient's drug treatment details. Patient must be at least 18 years of age. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.</p>	
Pegfilgrastim	C7822		<p>Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7843		<p>Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7843
	C9235		<p>Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9235
	C9303		<p>Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9303

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
Peginterferon alfa-2a	C5004		Chronic hepatitis C infection Must be treated in an accredited treatment centre. Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age. Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND Patient must have a contraindication to ribavirin; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must be limited to a maximum duration of 48 weeks. Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 5004
	C9603		Chronic hepatitis C infection Must be treated in an accredited treatment centre. Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age. Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND Patient must have a contraindication to ribavirin; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must be limited to a maximum duration of 48 weeks. Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9603
Pegvisomant	C7087		Acromegaly Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue;	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>AND</p> <p>The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.</p> <p>Somatostatin analogues include octreotide, lanreotide and pasireotide</p> <p>In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.</p> <p>Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).</p> <p>In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.</p>	
	C9041		<p>Acromegaly</p> <p>Initial treatment</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN); AND</p> <p>The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information; AND</p> <p>The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue. Somatostatin analogues include octreotide, lanreotide and pasireotide</p> <p>Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:</p> <ol style="list-style-type: none"> 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR 2) IGF-1 level is greater than the age- and sex-adjusted ULN. <p>If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.</p> <p>If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.</p> <p>In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be</p>	Compliance with Written Authority Required procedures

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			<p>withdrawn at least 8 weeks prior to the assessment of remission.</p> <p>Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).</p> <p>Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.</p> <p>The authority application must be made in writing and must include:</p> <p>a) two completed authority prescription forms ; and</p> <p>b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and</p> <p>c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and</p> <p>d) a recent result of the IGF-1 level and the date of assessment ; and</p> <p>e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide</p> <p>No increase in the maximum quantity or number of units may be authorised for the loading dose.</p>	
Plerixafor	C4549		<p>Mobilisation of haematopoietic stem cells</p> <p>The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND</p> <p>Patient must have lymphoma; OR</p> <p>Patient must have multiple myeloma; AND</p> <p>Patient must require autologous stem cell transplantation; AND</p> <p>Patient must have failed previous stem cell collection; OR</p> <p>Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR</p> <p>Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.</p> <p>Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4549
	C9329		<p>Mobilisation of haematopoietic stem cells</p> <p>The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND</p>	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have lymphoma; OR</p> <p>Patient must have multiple myeloma; AND</p> <p>Patient must require autologous stem cell transplantation; AND</p> <p>Patient must have failed previous stem cell collection; OR</p> <p>Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR</p> <p>Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.</p> <p>Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.</p>	procedures - Streamlined Authority Code 9329
Pomalidomide	C13746		<p>Multiple myeloma</p> <p>Initial treatment - dual therapy in combination with dexamethasone</p> <p>The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have undergone or be ineligible for a primary stem cell transplant; AND</p> <p>Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND</p> <p>Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p>	Compliance with Written Authority Required procedures

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			<p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and</p> <p>(2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C13755		<p>Multiple myeloma</p> <p>Continuing treatment - dual therapy in combination with dexamethasone</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p>	
	C13757		<p>Multiple myeloma</p> <p>Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide; AND</p> <p>Patient must have undergone or be ineligible for a stem cell transplant.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
	C13768		<p>Multiple myeloma</p> <p>Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p>	Compliance with Authority Required procedures

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			<p>AND</p> <p>The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
Raltegravir	C4454		<p>HIV infection</p> <p>Continuing</p> <p>Patient must have previously received PBS-subsidised therapy for HIV infection; AND</p> <p>The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		<p>HIV infection</p> <p>Initial</p> <p>Patient must be antiretroviral treatment naïve; AND</p> <p>The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Ravulizumab	C13459		<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Return from PBS-subsidised pegcetacoplan - induction doses</p> <p>Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND</p> <p>Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have developed resistance or intolerance to pegcetacoplan; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	
	C14476		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Subsequent Continuing Treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; OR Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.</p>	Compliance with Written Authority Required procedures
	C14477		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 1 (new patient) induction dose Patient must not have received prior treatment with this drug for this condition; AND Patient must have a diagnosis of PNH established by flow cytometry; AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L)</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			(ii) Platelets (x10 ⁹ /L) (iii) White Cell Count (x10 ⁹ /L) (iv) Reticulocytes (x10 ⁹ /L) (v) Neutrophils (x10 ⁹ /L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
	C14530		Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather (transition from non-PBS-subsidised treatment) Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab; AND Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to	Compliance with Written Authority Required procedures

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			<p>60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C14531		<p>Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided: (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)</p>	Compliance with Written Authority Required procedures
	C14565		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab; AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information</p> <p>At the time of the authority application, details (result and date of result) of the following</p>	

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			<p>monitoring requirements must be provided:</p> <ul style="list-style-type: none"> (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5 	
	C14586		<p>Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab - induction dose Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan. Must be treated by a haematologist; OR Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.</p>	Compliance with Written Authority Required procedures
	C14744		<p>Atypical haemolytic uraemic syndrome (aHUS) Switch from PBS-subsidised eculizumab (all phases) - loading dose Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised eculizumab under the 'Continuing</p>	Compliance with Written Authority Required procedures

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			<p>treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised eculizumab under the 'Recommendment of treatment' restriction for this condition; OR Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommendation of treatment' restriction for this condition; AND Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND Patient must not receive more than 2 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. The application must indicate the most recent treatment phase that the patient is switching from. For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include all of the following: (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted.</p>	
	C14746		<p>Atypical haemolytic uraemic syndrome (aHUS) Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have previously received non-PBS-subsidised therapy with this drug for this condition; AND Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS supply was commenced, the patient: (i) had active and progressing thrombotic microangiopathy (TMA) caused by aHUS; (ii) had ADAMTS-13 activity of greater than or equal to 10% on a blood sample not confounded by</p>	Compliance with Written Authority Required procedures

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			<p>any plasma exchange or infusion; (iii) had a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days of commencing ravulizumab treatment; (iv) had clinical features of active organ damage or impairment; AND Patient must have demonstrated ongoing treatment response with ravulizumab for this condition if received at least 26 weeks of initial non-PBS-subsidised therapy; AND Patient must not have experienced treatment failure with ravulizumab for this condition if they have received at least 26 weeks of initial non-PBS-subsidised therapy.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. Evidence of active and progressing TMA is defined by the following:</p> <p>(1) A platelet count of less than $150 \times 10^9/L$; and evidence of at least two of the following:</p> <ul style="list-style-type: none"> (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; or <p>(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and</p> <p>(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:</p> <p>(a) kidney impairment as demonstrated by one or more of the following:</p> <ul style="list-style-type: none"> (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; (iv) a renal biopsy consistent with aHUS; <p>(b) onset of TMA-related neurological impairment;</p> <p>(c) onset of TMA-related cardiac impairment;</p> <p>(d) onset of TMA-related gastrointestinal impairment;</p> <p>(e) onset of TMA-related pulmonary impairment.</p> <p>Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical</p>	

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			<p>measures.</p> <p>The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following:</p> <ol style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A detailed cover letter from the prescriber; (4) A measurement of body weight at the time of application; (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; (6) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days of initiating treatment with non-PBS-subsidised ravulizumab; (7) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of commencement of non-PBS-subsidised ravulizumab; (8) For patients who have received at least 26 weeks of ravulizumab treatment, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application. 	
	C14747		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Extended continuing treatment</p> <p>Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; OR</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; OR</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition; AND</p> <p>Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR</p> <p>Patient must have severe TMA-related neurological impairment; OR</p> <p>Patient must have severe TMA-related gastrointestinal impairment; OR</p> <p>Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR</p> <p>Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR</p> <p>Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab; AND</p> <p>Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following:</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is:</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a</p>	

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			<p>PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following:</p> <ol style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of multiple episodes of aHUS before commencing ravulizumab treatment, if applicable; (7) A history of kidney transplant, if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; (10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application; (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved; (12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.</p>	
	C14748		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Balance of Supply - maintenance doses</p> <p>Patient must have received PBS-subsidised loading dose of ravulizumab for this condition for this current treatment phase; AND</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND</p> <p>Patient must have received insufficient therapy to complete the maximum allowable treatment under their specified treatment phase; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the relevant treatment phase.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion and must have been submitted to Services Australia within 13 days of commencement of ravulizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p>	
	C14749		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Continuing treatment</p> <p>Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; OR</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; OR</p> <p>Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition; AND</p> <p>Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must not receive more than 72 weeks of ravulizumab treatment in total under this</p>	Compliance with Written Authority Required procedures

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			<p>restriction; OR</p> <p>Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment; AND</p> <p>Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following:</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is:</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following:</p> <p>(1) A completed authority prescription form(s);</p>	

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			<p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(7) An inclusion of the individual consequences of recurrent disease, if applicable;</p> <p>(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p> <p>(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;</p> <p>(10) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.</p>	
	C14780		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Initial treatment - Initial (new patient) loading dose</p> <p>Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS;</p> <p>AND</p> <p>Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L; AND</p> <p>Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days; AND</p> <p>Patient must have clinical features of active organ damage or impairment; AND</p> <p>Patient must not receive more than 2 weeks of treatment under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. Evidence of active and progressing TMA is defined by the following:</p> <p>(1) A platelet count of less than $150 \times 10^9/L$; and evidence of at least two of the following:</p> <ul style="list-style-type: none"> (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; or <p>(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and</p> <p>(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:</p> <ul style="list-style-type: none"> (a) kidney impairment as demonstrated by one or more of the following: <ul style="list-style-type: none"> (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; (iv) a renal biopsy consistent with aHUS; (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. <p>Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.</p> <p>The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following:</p> <ul style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A detailed cover letter from the prescriber; 	

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			<p>(4) A measurement of body weight at the time of application;</p> <p>(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;</p> <p>(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply;</p> <p>(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;</p> <p>(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;</p> <p>(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.</p> <p>Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.</p>	
	C14791		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Recommencement of treatment</p> <p>Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised C5 inhibitor for this condition; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count $<150 \times 10^9/L$); OR (iii) TMA-related organ impairment including on recent biopsy.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this</p>	Compliance with Written Authority Required procedures

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			<p>pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include all of the following: (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS if applicable; (6) A history of multiple episodes of aHUS following the treatment break, if applicable; (7) A history of kidney transplant if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of TMA-related organ damage including current</p>	

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			<p>(within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;</p> <p>(10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;</p> <p>(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;</p> <p>(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>Two authority prescription forms will be required to cover for the 26 weeks of recommencement therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.</p>	
	C14797		<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Continuing recommencement of treatment</p> <p>Patient must have received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Recommencement treatment' restriction for this condition; OR</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Continuing recommencement treatment' restriction for this condition; AND</p> <p>Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count,</p>	Compliance with Written Authority Required procedures

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			<p>(ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following: a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought. A treatment failure is defined as a patient who is: (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include all of the following: (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of multiple episodes of aHUS before recommencing ravulizumab treatment, if applicable; (7) A history of kidney transplant if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease, if applicable; (9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; (10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for</p>	

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			continuing ravulizumab is severe extra-renal complications that have significantly improved; (11) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab	
Ribavirin	C5957		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.	Compliance with Authority Required procedures
Rifabutin	C6350		Mycobacterium avium complex infection Patient must be human immunodeficiency virus (HIV) positive.	Compliance with Authority Required procedures - Streamlined Authority Code 6350
	C6356		Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 6356
	C9560		Mycobacterium avium complex infection Patient must be human immunodeficiency virus (HIV) positive.	Compliance with Authority Required procedures - Streamlined Authority Code 9560
	C9622		Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 9622

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Rilpivirine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Riociguat	C13502		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C13514		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	
	C13515		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg,</p>	Compliance with Written Authority Required procedures

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			<p>with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	
	C15271		<p>Chronic thromboembolic pulmonary hypertension (CTEPH)</p> <p>Continuing treatment</p>	<p>Compliance with Authority Required</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must demonstrate stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be at least 18 years of age. Response to this drug is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease. Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. <p>The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records. The test results conducted for continuing treatment must be no more than 2 months old at the time of application. The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. The maximum quantity per prescription must be based on the dosage recommendations in the</p>	procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment. A maximum of 5 repeats will be authorised. Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.	
	C15272		Chronic thromboembolic pulmonary hypertension (CTEPH) Balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be at least 18 years of age.	Compliance with Authority Required procedures
	C15274		Chronic thromboembolic pulmonary hypertension (CTEPH) Initial treatment Patient must have WHO Functional Class II, III or IV CTEPH; AND The condition must be inoperable by pulmonary endarterectomy; OR The condition must be recurrent or persistent following pulmonary endarterectomy; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be at least 18 years of age. CTEPH that is inoperable by pulmonary endarterectomy is defined as follows: (a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm-5 measured at least 90 days after start of full anticoagulation; and (b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation. CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows: RHC demonstrating a PVR of greater than 300 dyn*sec*cm-5 measured at least 180 days following pulmonary endarterectomy. Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>demonstrating the dysfunction must be documented in the patient's medical records. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) the results from the 3 tests below, to establish baseline measurements, where available:</p> <p>(i) RHC composite assessment, and</p> <p>(ii) ECHO composite assessment, and</p> <p>(iii) 6 Minute Walk Test (6MWT); and</p> <p>(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or</p> <p>(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or</p> <p>(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:</p> <p>(1) RHC plus ECHO composite assessments;</p> <p>(2) RHC composite assessment plus 6MWT;</p> <p>(3) RHC composite assessment only.</p> <p>In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.</p> <p>The test results provided must not be more than 2 months old at the time of application. Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information.</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.</p> <p>The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
Risdiplam	C14368		<p>Spinal muscular atrophy (SMA)</p> <p>Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood</p> <p>Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood; AND</p> <p>Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; OR</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access); AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>or equal to 16 hours per day.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:</p> <p>(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,</p> <p>(ii) Proximal weakness,</p> <p>(iii) Hypotonia,</p> <p>(iv) Absence of deep tendon reflexes,</p> <p>(v) Failure to gain weight appropriate for age,</p> <p>(vi) Any active denervation or chronic neurogenic changes found on electromyography,</p> <p>(vii) A compound muscle action potential below normative values for an age-matched child.</p> <p>In this authority application, confirm:</p> <p>(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,</p> <p>(2) which of the above (i to vii) (at least 1) were present during childhood,</p> <p>(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.</p>	
	C14372		<p>Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)</p> <p>Initial treatment</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic. Patient must be untreated with gene therapy. Patient must be 18 years of age or under. Defined signs and symptoms of type I SMA are: i) Onset before 6 months of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type II SMA are: i) Onset between 6 and 18 months; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Weakness in trunk righting/derotation; or v) Hypotonia; or vi) Absence of deep tendon reflexes; or vii) Failure to gain weight appropriate for age; or viii) Any active chronic neurogenic changes; or ix) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type IIIa SMA are: i) Onset between 18 months and 3 years of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. Application for authorisation of initial treatment must be in writing and must include:</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(a) a completed authority prescription form; and (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following: i) specification of SMA type (I, II or IIIa); and (ii) sign(s) and symptom(s) that the patient has experienced; and (iii) patient's age at the onset of sign(s) and symptom(s). The approved Product Information recommended dosing is as follows: (i) 16 days to less than 2 months of age: 0.15 mg/kg (ii) 2 months to less than 2 years of age: 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more: 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to: 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	
	C14392		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
	C14408		<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Initial PBS-subsidised treatment with this drug in a child</p> <p>Patient must be of an age that is prior to their 19th birthday at the time of this authority application;</p> <p>AND</p> <p>Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease;</p> <p>OR</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access); AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene;</p> <p>AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:</p> <p>(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,</p> <p>(ii) Proximal weakness,</p> <p>(iii) Hypotonia,</p> <p>(iv) Absence of deep tendon reflexes,</p> <p>(v) Any active denervation or chronic neurogenic changes found on electromyography,</p> <p>(vi) A compound muscle action potential below normative values for an age-matched child.</p> <p>In this authority application, confirm:</p> <p>(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,</p> <p>(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,</p> <p>(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
	C14420		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in an adult where treatment was initiated in adulthood</p>	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR The treatment must be occurring within the first 104 weeks from the first administered dose; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response. A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline. PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present. Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records. In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).</p>	procedures
	C14435		Spinal muscular atrophy (SMA)	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA. Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples); AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.</p> <p>Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.</p> <p>Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.</p> <p>Definition:</p> <p>Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.</p> <p>0. Absence of developmental states (1 to 9) listed below:</p> <p>1. Rolls from side to side on back;</p>	Authority Required procedures

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			<p>2. Child holds head erect for at least 3 seconds unsupported;</p> <p>3. Sitting, but with assistance;</p> <p>4. Sitting without assistance:</p> <p>(a) Child sits up straight with the head erect for at least 10 seconds;</p> <p>(b) Child does not use arms or hands to balance body or support position.</p> <p>5. Hands and knees crawling:</p> <p>(a) Child alternately moves forward or backwards on hands and knees;</p> <p>(b) The stomach does not touch the supporting surface;</p> <p>(c) There are continuous and consecutive movements at least 3 in a row.</p> <p>6. Standing with assistance:</p> <p>(a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;</p> <p>(b) The body does not touch the stable object, and the legs support most of the body weight;</p> <p>(c) Child thus stands with assistance for at least 10 seconds.</p> <p>7. Standing alone:</p> <p>(a) Child stands in upright position on both feet (not on the toes) with the back straight;</p> <p>(b) The leg supports 100% of the child's weight;</p> <p>(c) There is no contact with a person or object;</p> <p>(d) Child stands alone for at least 10 seconds.</p> <p>8. Walking with assistance:</p> <p>(a) Child is in an upright position with the back straight;</p> <p>(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;</p> <p>(c) One leg moves forward while the other supports part of the body weight;</p> <p>(d) Child takes at least 5 steps in this manner.</p> <p>9. Walking alone:</p> <p>(a) Child takes at least 5 steps independently in upright position with the back straight;</p> <p>(b) One leg moves forward while the other supports most of the body weight;</p> <p>(c) There is no contact with a person or object.</p> <p>Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)).</p> <p>Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg (ii) 2 months to less than 2 years of age: 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	
	C14458		<p>Pre-symptomatic spinal muscular atrophy (SMA) Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA) Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA. The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND The condition must be pre-symptomatic; AND The treatment must be given concomitantly with best supportive care for this condition; AND Patient must be untreated with gene therapy. Patient must be aged under 36 months prior to commencing treatment. Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include: (a) a completed authority prescription form; and (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following: (i) confirmation of genetic diagnosis of SMA; and</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg (ii) 2 months to less than 2 years of age: 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	
	C15095		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg (ii) 2 months to less than 2 years of age: 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:</p> <p>1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	
Ritonavir	C4454		<p>HIV infection</p> <p>Continuing</p> <p>Patient must have previously received PBS-subsidised therapy for HIV infection; AND</p> <p>The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		<p>HIV infection</p> <p>Initial</p> <p>Patient must be antiretroviral treatment naïve; AND</p> <p>The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Romiplostim	C13396		<p>Severe thrombocytopenia</p> <p>Second or Subsequent Continuing treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction; AND</p> <p>Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p> <p>The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.</p> <p>Authority approval will not be given for doses higher than 10 micrograms/kg/week</p>	
	C14098		<p>Severe thrombocytopenia Initial treatment - New patient</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.</p> <p>The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.</p> <p>Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.</p> <p>Authority approval will not be given for doses higher than 10 micrograms/kg/week</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details of a platelet count supporting the diagnosis of ITP.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			latest version is located on the website specified in the Administrative Advice). The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.	
	C14099		Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses higher than 10 micrograms/kg/week The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.	Compliance with Authority Required procedures
	C14149		Severe thrombocytopenia Balance of supply or change of therapy The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR</p> <p>Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.</p> <p>Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.</p>	
Ruxolitinib	C13876	P13876	<p>Grade II to IV acute graft versus host disease (aGVHD)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.</p> <p>Must be treated by a haematologist; OR</p> <p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR</p> <p>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.</p> <p>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p> <p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>Tapering the dose of corticosteroids should be considered in patients with responding disease.</p> <p>Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13876
	C13892	P13892	Grade II to IV acute graft versus host disease (aGVHD)	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response. Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	<p>Authority Required procedures - Streamlined Authority Code 13892</p>
	C13907	P13907	<p>Grade II to IV acute graft versus host disease (aGVHD) Initial treatment Patient must have received prior systemic steroid treatment for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment. Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13907</p>

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			<p>(MAGIC) criteria (Harris et al., 2016). Steroid-refractory disease is defined as: (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD. Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria: (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal. Details of prior steroid use should be documented in the patient's medical records. A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
	C13911	P13911	Grade II to IV acute graft versus host disease (aGVHD) Initial treatment	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have received prior systemic steroid treatment for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment. Must be treated by a haematologist; OR Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Steroid-refractory disease is defined as: (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD. Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria: (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal. Details of prior steroid use should be documented in the patient's medical records. A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p>	<p>procedures - Streamlined Authority Code 13911</p>

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			(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
Selexipag	C11193		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND The treatment must not be as monotherapy. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred: (i) Hospitalisation due to worsening PAH; (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status; (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy; (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH; (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.	Compliance with Authority Required procedures
	C11195		Pulmonary arterial hypertension (PAH)	Compliance with

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment following dose titration</p> <p>Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR</p> <p>Patient must have WHO Functional Class IV PAH at treatment initiation with this drug; AND</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR</p> <p>The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND</p> <p>Patient must have completed the dose titration phase; AND</p> <p>The treatment must not be as monotherapy.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.</p> <p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or</p> <p>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p>	Authority Required procedures
	C11261		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial treatment - dose titration</p>	Compliance with Authority Required

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			<p>Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy; AND</p> <p>Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR</p> <p>Patient must have WHO Functional Class IV PAH at treatment initiation with this drug; AND</p> <p>The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks; AND</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR</p> <p>The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND</p> <p>The treatment must not be as monotherapy.</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, eproprostenol, iloprost, riociguat.</p> <p>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.</p> <p>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or</p> <p>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p>	procedures
Selinexor	C14021	P14021	<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week</p> <p>The condition must be confirmed by a histological diagnosis; AND</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR</p> <p>Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.</p> <p>Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p>	

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			<p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.</p> <p>Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p>	
	C14023	P14023	<p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 100 mg per week</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p> <p>AND</p> <p>Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR</p> <p>Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone;</p> <p>AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			g per L serum M protein.	
	C14024	P14024	<p>Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 100 mg per week The condition must be confirmed by a histological diagnosis; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p>	Compliance with Authority Required procedures
	C14031	P14031	<p>Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 160 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for</p>	Compliance with Authority Required procedures

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			<p>this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
	C14039	P14039	<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment - Dose requirement of 160 mg per week</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p>	
	C14045	P14045	<p>Relapsed and/or refractory multiple myeloma Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
Sevelamer	C5530		Hyperphosphataemia Initiation and stabilisation	Compliance with Authority Required

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			<p>The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.</p>	<p>procedures - Streamlined Authority Code 5530</p>
	C9762		<p>Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9762</p>
Sildenafil	C11229		<p>Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'). Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b)</p>	<p>Compliance with Authority Required procedures</p>

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			<p>bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p> <p>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or</p> <p>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13482		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at</p>	Compliance with Authority Required procedures

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			<p>the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13484		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	
	C13569		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures

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	C13570		<p>Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid. Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
	C13572		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C13573		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of</p>	Compliance with Authority Required procedures

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			<p>the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	
	C13629		<p>Pulmonary arterial hypertension (PAH) Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p>	Compliance with Written Authority Required procedures

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			<p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p>	
Siltuximab	C12585		<p>Idiopathic multicentric Castleman disease (iMCD)</p> <p>Initial treatment</p> <p>Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records; AND</p> <p>The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human</p>	Compliance with Authority Required procedures

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			immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist; AND Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; OR Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription. Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.	
	C12594		Idiopathic multicentric Castleman disease (iMCD) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.	Compliance with Authority Required procedures
Sirolimus	C5795		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5795
	C9914		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9914
Sofosbuvir with velpatasvir	C5969		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND	Compliance with Authority Required procedures

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			The treatment must be limited to a maximum duration of 12 weeks.	
Sofosbuvir with velpatasvir and voxilaprevir	C10248		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. The application must include details of the prior treatment regimen containing an NS5A inhibitor.	Compliance with Authority Required procedures
Sucroferric oxyhydroxide	C5530		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5530
	C9762		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9762
Tacrolimus	C5569		Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Authority Required procedures - Streamlined Authority Code 5569

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	C9697		Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit; AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Authority Required procedures - Streamlined Authority Code 9697
Tadalafil	C11229		<p>Pulmonary arterial hypertension (PAH) Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'). Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. The authority application for selexipag must be approved prior to the authority application for this agent. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of</p>	Compliance with Authority Required procedures

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			treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C13482		<p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C13484		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority</p>	

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			<p>application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
	C13569		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
	C13570		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C13572		<p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
	C13573		<p>Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
	C13629		Pulmonary arterial hypertension (PAH)	Compliance with Written

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			<p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH. Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition: (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted: - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is: - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT;</p>	Authority Required procedures

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			<p>- RHC composite assessment only. In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:</p> <p>- ECHO composite assessment plus 6MWT; - ECHO composite assessment only.</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p>	
Teduglutide	C11999		<p>Type III Short bowel syndrome with intestinal failure Initial treatment - balance of supply Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment; AND The treatment must provide no more than the balance of up to 12 months of treatment.</p>	Compliance with Authority Required procedures
	C14534		<p>Type III Short bowel syndrome with intestinal failure Initial treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have short bowel syndrome with intestinal failure following major surgery; AND Patient must have a history of dependence on parenteral support for at least 12 months; AND Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks; AND Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years; AND The treatment must not exceed 12 months under this restriction; AND Patient must not have previously received PBS-subsidised treatment with this drug for this</p>	Compliance with Written Authority Required procedures

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			<p>condition. Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either: (i) for a patient of any age, the mean number of days of parenteral support per week (ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg. Determine the mean over any given 4 week period prior to this authority application. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i). Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application. A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
	C14632		<p>Type III Short bowel syndrome with intestinal failure Continuing treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; OR Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline; OR The treatment must be resuming after a break in therapy, but before the break in therapy occurred, a reduction in parenteral support relative to baseline had been occurring to an extent as stated as above. Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application. The current mean number of days of parenteral support is calculated as the mean number of days</p>	Compliance with Written Authority Required procedures

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			<p>in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.</p> <p>The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.</p> <p>From 1 September 2021</p> <p>Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both:</p> <p>(i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and</p> <p>(ii) the current value (observed over a 4 week timeframe)</p> <p>Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.</p> <p>Where treatment is resuming after a break in treatment with this drug, state parenteral support days/volume values as occurring prior to the break instead of current values.</p> <p>A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.</p> <p>Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
Tenofovir	C6980	P6980	<p>Chronic hepatitis B infection</p> <p>Patient must have cirrhosis; AND</p> <p>Patient must be nucleoside analogue naive; AND</p> <p>Patient must have detectable HBV DNA; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6980

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			less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	
	C6982	P6982	HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6982
	C6983	P6983	Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6983
	C6984	P6984	Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 6984
	C6992	P6992	Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 6992
	C6998	P6998	HIV infection Initial	Compliance with Authority Required

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			Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	procedures - Streamlined Authority Code 6998
	C10362	P10362	Chronic hepatitis B infection Patient must be in the third trimester of pregnancy; AND Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection.	Compliance with Authority Required procedures - Streamlined Authority Code 10362
Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Tenofovir with emtricitabine	C6985		HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6985
	C6986		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6986
Tenofovir with emtricitabine and efavirenz	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Tezacaftor with ivacaftor and ivacaftor	C12609		Cystic fibrosis - one residual function (RF) mutation Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in	Compliance with Written Authority Required procedures

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			<p>consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 12 years of age or older. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort; Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin; Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C12614		<p>Cystic fibrosis - homozygous for the F508del mutation Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with</p>	Compliance with Written Authority Required procedures

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			<p>expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 12 years of age or older. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort; Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin; Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C12630		<p>Cystic fibrosis - one residual function (RF) mutation Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with</p>	Compliance with Written Authority Required procedures

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			<p>ivacaftor; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities. Patient must be 12 years of age or older. For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort; Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin; Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and (3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and (4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
	C12635		<p>Cystic fibrosis - homozygous for the F508del mutation Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in</p>	<p>Compliance with Written Authority Required procedures</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.</p> <p>Patient must be 12 years of age or older.</p> <p>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.</p> <p>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.</p> <p>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:</p> <p>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;</p> <p>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;</p> <p>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.</p> <p>The authority application must be in writing and must include:</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	

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Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
Thalidomide	C5914		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5914
	C9290		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9290
Tocilizumab	C9380		Severe active juvenile idiopathic arthritis Continuing Treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C9386		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
	C9407		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR</p> <p>Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Active joints are defined as:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count must be no more than 4 weeks old at the time of this application.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved</p>	Compliance with Written Authority Required procedures

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Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C9417		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply</p> <p>Must be treated by a paediatric rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C9494		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C9495		<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C10570		<p>Systemic juvenile idiopathic arthritis</p> <p>Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p>	Compliance with Authority Required procedures
	C12163		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C12436		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)</p> <p>Must be treated by a paediatric rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND</p> <p>Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.</p> <p>If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12450		Severe active juvenile idiopathic arthritis	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND</p> <p>Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.</p> <p>If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p> <p>An adequate response to treatment is defined as:</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following:</p> <p>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or</p> <p>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or</p> <p>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p>	<p>Authority Required procedures</p>

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C12451		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological</p>	Compliance with Written Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>medicine to tocilizumab after resolution of the critical shortage of tocilizumab)</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND</p> <p>Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.</p> <p>If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p> <p>An adequate response to treatment is defined as:</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline,</p>	procedures

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			<p>where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14082		<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14082

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			<p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14083		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology</p>	Compliance with Authority Required procedures

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			<p>treatment centre.</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Active joints are defined as:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this</p>	

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			treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14085		<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND</p> <p>Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR</p> <p>Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must be under 18 years of age.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.</p> <p>The following reports must be documented in the patient's medical records where appropriate:</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for</p>	Compliance with Authority Required procedures

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			<p>two infusions (one month's supply). A separate authority approval is required for each strength requested.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C14091		<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (retrial or commencement of treatment after a break of less than 12 months)</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) in a patient with polyarticular course disease:</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:</p> <ul style="list-style-type: none"> - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not 	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms:</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.</p> <p>The following reports must be documented in the patient's medical records where appropriate:</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to re-trial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14093		<p>Systemic juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p> <p>AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14093

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			<p>Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) in a patient with polyarticular course disease:</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:</p> <ul style="list-style-type: none"> - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). <p>(b) in a patient with refractory systemic symptoms:</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>treatment.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14145		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>An adequate response to treatment is defined as:</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological</p>	Compliance with Authority Required procedures

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			<p>medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14148		<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR</p> <p>Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR</p> <p>Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Patient must be under 18 years of age.</p> <p>Must be treated by a rheumatologist; OR</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>The following criteria indicate failure to achieve an adequate response to prior methotrexate</p>	Compliance with Authority Required procedures

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			<p>therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:</p> <p>(a) an active joint count of at least 2 active joints; and</p> <p>(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or</p> <p>(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p>	

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			<p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and (b) the details of prior treatment including dose and duration of treatment.</p> <p>The following reports must be documented in the patient's medical records where appropriate:</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p>	
	C14162		<p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age.</p>	Compliance with Authority Required procedures

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			<p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of</p>	

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			that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C14164		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these	Compliance with Authority Required procedures - Streamlined Authority Code 14164

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			<p>timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
	C14179		<p>Systemic juvenile idiopathic arthritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. The assessment of response to treatment must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14179

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			<p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C14485		<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14485</p>

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			<p>Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14487		<p>Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p>	

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			<p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14488		<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
	C14489		<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p>	Compliance with Written Authority Required

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			<p>Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from</p>	procedures

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			<p>cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14491		<p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses</p>	Compliance with Written Authority Required procedures

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			<p>specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must</p>	

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			<p>state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
	C14507		<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment - balance of supply</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures
	C14538		Severe active rheumatoid arthritis	Compliance with Written

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the</p>	Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
	C14621		<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14621

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
Ustekinumab	C9655		<p>Severe Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for</p>	

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			<p>treatment that would otherwise extend the initial treatment period.</p> <p>To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C9656		<p>Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.</p> <p>Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C9710		<p>Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>of assessment of the patient's condition if relevant; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</p> <p>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iv) the date of the most recent clinical assessment.</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.</p> <p>Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C13975		<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND</p> <p>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2</p>	Compliance with Written Authority Required procedures

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			<p>mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; OR</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND</p> <p>The treatment must not exceed a single dose to be administered at week 0 under this restriction. Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p>	
	C13976		<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>The treatment must not exceed a single dose to be administered at week 0 under this restriction. Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
	C14010		<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; OR</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND</p> <p>The treatment must not exceed a single dose to be administered at week 0 under this restriction.</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
	C14758		<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological</p>	Compliance with Written Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Applications for authorisation must be made in writing and must include: (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats. The most recent fistula assessment must be no more than 4 weeks old at the time of application. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the</p>	<p>procedures</p>

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			<p>subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised</p> <p>Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p>	
	C14787		<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have an externally draining enterocutaneous or rectovaginal fistula.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(1) two completed authority prescription forms; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised</p> <p>Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p>	
	C14801		<p>Complex refractory Fistulising Crohn disease</p> <p>Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]</p>	Compliance with Authority Required procedures
Valaciclovir	C5975		<p>Cytomegalovirus infection and disease</p> <p>Prophylaxis</p> <p>Patient must have undergone a renal transplant; AND</p> <p>Patient must be at risk of cytomegalovirus disease.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5975
	C9267		<p>Cytomegalovirus infection and disease</p> <p>Prophylaxis</p>	Compliance with Authority Required

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	procedures - Streamlined Authority Code 9267
Valganciclovir	C4980		Cytomegalovirus retinitis Patient must have HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4980
	C4989		Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 4989
	C9316		Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9316
Vedolizumab	C9738		Moderate to severe ulcerative colitis Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.	
	C9771		Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.	Compliance with Authority Required procedures
	C12080		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND</p> <p>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; OR</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND</p> <p>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.</p> <p>Patient must be aged 18 years or older.</p> <p>Application for authorisation of initial treatment must be in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>time of application.</p> <p>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
	C12083		<p>Severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must be aged 18 years or older.</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND</p> <p>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR</p> <p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</p> <p>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iv) the date of the most recent clinical assessment.</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>the following:</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted</p>	

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			<p>following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C12135		<p>Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>number of vials, to provide for a single infusion of 300 mg per dose. Up to a maximum of 2 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C12137		<p>Severe Crohn disease Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by</p>	Compliance with Written Authority Required procedures

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Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>extensive small intestine disease; OR</p> <p>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or</p> <p>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and</p> <p>(iii) the date of clinical assessment.</p> <p>All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.</p>	
	C12179		<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.</p> <p>Patient must be aged 18 years or older.</p> <p>Application for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting</p>	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.</p> <p>Up to a maximum of 2 repeats will be authorised.</p> <p>Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p>	
	C12219		Moderate to severe ulcerative colitis	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the</p>	Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
	C12220		<p>Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>this condition during the current treatment cycle; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C12221		<p>Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have evidence of intestinal inflammation; OR</p> <p>Patient must be assessed clinically as being in a high faecal output state; OR</p> <p>Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND</p> <p>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.</p> <p>Patient must be aged 18 years or older.</p> <p>Applications for authorisation must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iii) the date of the most recent clinical assessment.</p> <p>Evidence of intestinal inflammation includes:</p> <p>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
Zidovudine	C4454		<p>HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		<p>HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Zoledronic acid	C5605	P5605	<p>Bone metastases The condition must be due to breast cancer.</p>	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
				procedures - Streamlined Authority Code 5605
	C5703	P5703	Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5703
	C5704	P5704	Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5704
	C5735	P5735	Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5735
	C9268	P9268	Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9268
	C9304	P9304	Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9304
	C9317	P9317	Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9317
	C9328	P9328	Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9328
	C14729	P14729	Adjuvant management of breast cancer Patient must be post-menopausal. Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for	Compliance with Authority Required procedures - Streamlined

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			more than 36 months.	Authority Code 14729
	C14735	P14735	Adjuvant management of breast cancer Patient must be post-menopausal. Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.	Compliance with Authority Required procedures - Streamlined Authority Code 14735

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)	30 Mar 2021 (F2021L00374)	1 Apr 2021 (s 2(1) item 1)	
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2021 (PB 28 of 2021)	31 Mar 2021 (F2021L00400)	1 Apr 2021 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2021 (PB 42 of 2021)	30 Apr 2021 (F2021L00523)	1 May 2021 (s 2)	—
National Health (Highly specialised drugs program) Special Arrangement Amendment (June Update) Instrument 2021 (PB 50 of 2021)	28 May 2021 (F2021L00667)	1 June 2021 (s 2)	—
National Health (Highly specialised drugs program) Special Arrangement Amendment (July Update) Instrument 2021 (PB 64 of 2021)	30 June 2021 (F2021L00910)	1 July 2021 (s 2)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2021 (PB 79 of 2021)	31 July 2021 (F2021L01055)	1 Aug 2021 (s 2)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (September Update) Instrument 2021 (PB 91 of 2021)	31 Aug 2021 (F2021L01221)	1 Sept 2021 (s 2(1) item 1)	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2021 (PB 101 of 2021)	30 Sept 2021 (F2021L01375)	1 Oct 2021 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (November Update) Instrument 2021 (PB 113 of 2021)	31 Oct 2021 (F2021L01488)	1 Nov 2021 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2021 (PB 121 of 2021)	30 Nov 2021 (F2021L01645)	1 Dec 2021 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (January Update) Instrument 2021 (PB 131 of 2021)	24 Dec 2021 (F2021L01896)	1 Jan 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (February Update) Instrument 2022 (PB 5 of 2022)	31 Jan 2022 (F2022L00094)	1 Feb 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (March Update) Instrument 2022 (PB 14 of 2022)	28 Feb 2022 (F2022L00206)	1 Mar 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2022 (PB 27 of 2022)	31 Mar 2022 (F2022L00456)	1 Apr 2022 (s 2(1) item 1)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2022 (PB 37 of 2022)	29 Apr 2022 (F2022L00646)	1 May 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (June Update) Instrument 2022 (PB 47 of 2022)	31 May 2022 (F2022L00732)	1 June 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July Update) Instrument 2022 (PB 57 of 2022)	29 June 2022 (F2022L00875)	1 July 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2022 (PB 70 of 2022)	29 July 2022 (F2022L01019)	1 Aug 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (September Update) Instrument 2022 (PB 81 of 2022)	26 Aug 2022 (F2022L01116)	1 Sept 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (Rituximab) Instrument 2022 (PB 80 of 2022)	30 Aug 2022 (F2022L01139)	1 Sept 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2022 (PB 89 of 2022)	30 Sept 2022 (F2022L01293)	1 Oct 2022 (s 2(1) item 1)	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (November Update) Instrument 2022 (PB 102 of 2022)	31 Oct 2022 (F2022L01415)	1 Nov 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2022 (PB 114 of 2022)	30 Nov 2022 (F2022L01549)	1 Dec 2022 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (January Update) Instrument 2022 (PB 123 of 2022)	23 Dec 2022 (F2022L01763)	1 Jan 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (February Update) Instrument 2023 (PB 4 of 2023)	31 Jan 2023 (F2023L00063)	1 Feb 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (March Update) Instrument 2023 (PB 14 of 2023)	28 Feb 2023 (F2023L00166)	1 Mar 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2023 (PB 24 of 2023)	31 Mar 2023 (F2023L00392)	1 Apr 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2023 (PB 37 of 2023)	28 Apr 2023 (F2023L00491)	1 May 2023 (s 2(1) item 1)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023 (PB 17 of 2023)	1 May 2023 (F2023L00511)	Sch 2 (items 4, 5): 1 June 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (June Update) Instrument 2023 (PB 46 of 2023)	31 May 2023 (F2023L00653)	1 June 2023 (s 2(1) item 1)	—
National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023 (PB 57 of 2023)	23 June 2023 (F2023L00843)	Sch 1: 1 July 2023 (s 2(1) item 2)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July Update) Instrument 2023 (PB 58 of 2023)	30 June 2023 (F2023L00908)	1 July 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2023 (PB 71 of 2023)	31 July 2023 (F2023L01049)	1 Aug 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (September Update) Instrument 2023 (PB 84 of 2023)	31 Aug 2023 (F2023L01155)	1 Sept 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (October Update) Instrument 2023 (PB 94 of 2023)	29 Sept 2023 (F2023L01333)	1 Oct 2023 (s 2(1) item 1)	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (November Update) Instrument 2023 (PB 107 of 2023)	31 Oct 2023 (F2023L01445)	1 Nov 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2023 (PB 116 of 2023)	30 Nov 2023 (F2023L01584)	1 Dec 2023 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (January Update) Instrument 2023 (PB 132 of 2023)	22 Dec 2023 (F2023L01745)	1 Jan 2024 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (February Update) Instrument 2024 (PB 5 of 2024)	31 Jan 2024 (F2024L00124)	1 Feb 2024 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (March Update) Instrument 2024 (PB 18 of 2024)	29 Feb 2024 (F2024L00241)	1 Mar 2024 (s 2(1) item 1)	—
National Health Legislation (Repeal and Consequential Amendments) Instrument 2024 (PB 36 of 2024)	28 Mar 2024 (F2024L00412)	Sch 2 (items 25–34): 1 Apr 2024 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2024 (PB 30 of 2024)	28 Mar 2024 (F2024L00413)	1 Apr 2024 (s 2(1) item 1)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (May Update) Instrument 2024 (PB 43 of 2024)	30 Apr 2024 (F2024L00505)	1 May 2024 (s 2(1) item 1)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (June Update) Instrument 2024 (PB 55 of 2024)	31 May 2024 (F2024L00606)	1 June 2024 (s 2(1) item 1)	—
National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024 (PB 66 of 2024)	27 June 2024 (F2024L00803)	Sch 1 (items 34–42): 1 July 2024 (s 2(1) item 2)	—
National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July Update) Instrument 2024 (PB 71 of 2024)	28 June 2024 (F2024L00821)	1 July 2024 (s 2(1) item 1)	—

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
Division 1	
s 2.....	rep LA s 48D
s 4.....	rep LA s 48C
s 6.....	am F2021L00400 ed C1 am F2021L01055; F2021L01221; F2022L00206; F2022L00456; F2022L00646; F2022L00875; F2022L01139; F2022L01293; F2022L01415; F2022L01549; F2022L01763; F2023L00843; F2023L00908; F2023L01155; F2024L00124; F2024L00412; F2024L00413; F2024L00505; F2024L00606; F2024L00803; F2024L00821
s 7.....	am F2023L00843; F2024L00412
s 8.....	am F2022L00206; F2022L01139; F2023L00843; F2024L00412
Part 2	
Division 1	
s 13.....	am F2022L01139; F2023L00843
Division 2	
s 14.....	am F2022L01139; F2023L00843 rep F2024L00412
s 15.....	(4) rep 1 July 2022 (s 17(3)) am F2022L01139; F2024L00412
s 16.....	am F2022L01139; F2024L00412
s 17.....	am F2021L01896 rep 1 July 2022 (s 17(3))
s 18.....	am F2022L01139
s 20.....	ed C1 am F2023L00843
s 21.....	am F2023L00843
s 23.....	am F2022L00206; F2023L00843
Division 3	
s 24.....	am F2023L00166
s 25.....	rs F2023L00511; F2023L00843
s 26.....	rs F2023L00843
Part 3	
Division 1	
s 28.....	am F2023L00843; F2024L00803
s 29.....	am F2024L00412

Endnote 4—Amendment history

Provision affected	How affected
Division 2	
s 30.....	am F2023L00843; F2024L00803
s 30A.....	ad F2023L00511
s 31.....	am F2023L00843; F2024L00803
s 32.....	am F2023L00843 ed C28
s 34.....	am F2023L00843
Part 3A	
Part 3A.....	ad F2024L00803
34A.....	ad F2024L00803
34B.....	ad F2024L00803
Part 4	
s 35.....	am F2023L00843
s 35A.....	ad F2024L00803
Part 5	
s 37.....	am F2023L00843; F2024L00803
Part 6	
Division 2	
Division 2.....	ad F2023L00843
s 39.....	ad F2023L00843
s 40.....	ad F2023L00843
s 41.....	ad F2023L00843
s 42.....	ad F2023L00843
s 43.....	ad F2023L00843
s 44.....	ad F2023L00843
s 45.....	ad F2023L00843
s 46.....	ad F2023L00843
s 47.....	ad F2023L00843
s 48.....	ad F2023L00843
s 49.....	ad F2023L00843
s 50.....	ad F2023L00843 am F2024L00412
Schedule 1	
Schedule 1.....	am F2021L00400; F2021L00523; F2021L00667; F2021L00910; F2021L01055; F2021L01221; F2021L01375; F2021L01488; F2021L01645; F2021L01896; F2022L00094; F2022L00206; F2022L00456; F2022L00646; F2022L00732; F2022L00875; F2022L01019; F2022L01116; F2022L01139 ed C18

Endnotes

Endnote 4—Amendment history

Provision affected	How affected
	am F2022L01293; F2022L01415; F2022L01549; F2022L01763; F2023L00063; F2023L00166; F2023L00392; F2023L00491; F2023L00653; F2023L00908; F2023L01049; F2023L01155; F2023L01333; F2023L01445; F2023L01584; F2023L01745; F2024L00124; F2024L00241; F2024L00413; F2024L00505; F2024L00606; F2024L00821
Schedule 2	
Schedule 2.....	am F2021L00400; F2021L00667; F2021L00910; F2021L01055; F2021L01221; F2021L01375; F2021L01488 rs F2021L01645 am F2022L00206; F2022L00456; F2022L00646; F2022L00732; F2022L00875; F2022L01019; F2022L01116; F2022L01139; F2022L01415; F2022L01549; F2022L01763; F2023L00063; F2023L00166; F2023L00392; F2023L00491; F2023L00653; F2023L00908; F2023L01333; F2023L01445; F2023L01584; F2023L01745; F2024L00241; F2024L00413; F2024L00505; F2024L00606; F2024L00821
Schedule 3	
Schedule 3.....	am F2021L00400; F2021L00667; F2021L00910; F2021L01055; F2021L01221; F2021L01375; F2021L01488; F2021L01645 ed C9 am F2022L00094; F2022L00206; F2022L00456; F2022L00646; F2022L00732; F2022L00875; F2022L01019; F2022L01116; F2022L01139; F2022L01293; F2022L01415; F2022L01549; F2022L01763; F2023L00063; F2023L00166; F2023L00392; F2023L00491; F2023L00653; F2023L00908; F2023L01155; F2023L01333; F2023L01445; F2023L01584; F2023L01745; F2024L00124; F2024L00241; F2024L00413; F2024L00505; F2024L00606; F2024L00821
Schedule 4.....	am F2021L00400 rep 1 July 2022 (s 17(3))
Schedule 5.....	rep LA s 48C