



**PB 27 of 2021**

## **National Health (Highly Specialised Drugs Program) Special Arrangement 2021**

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I, Adriana Platona, as delegate of the Minister for Health and Aged Care, make the following special arrangement.

Dated 25 March 2021

Adriana Platona  
First Assistant Secretary  
Technology Assessment and Access Division  
Department of Health

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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.

#### 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 April 2021.	1 April 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

#### 3 Authority

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

#### 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

#### 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.

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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.

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 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) azacitidine;
- (e) benralizumab;
- (f) bosentan;
- (g) eculizumab;
- (h) eltrombopag;
- (i) epoprostenol;
- (j) etanercept;
- (k) iloprost;
- (l) infliximab;
- (m) ivacaftor;
- (n) lenalidomide;
- (o) lumacaftor with ivacaftor;
- (p) macitentan;
- (q) mepolizumab;
- (r) midostaurin;
- (s) nusinersen;
- (t) omalizumab;
- (u) pasireotide;
- (v) pegvisomant;
- (w) pomalidomide;
- (x) riociguat;
- (y) rituximab;
- (z) romiplostim;
- (za) sildenafil;

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- (zb) tadalafil;
- (zc) teduglutide;
- (zd) tezacaftor with ivacaftor and ivacaftor;
- (ze) tocilizumab;
- (zf) ustekinumab;
- (zg) 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;
- (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.

**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.

**eligible patient** has the meaning given by section 8.

**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 2012* (PB 71 of 2012).

**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) interferon alfa-2a;
- (d) lamivudine;
- (e) tenofovir.

**medication for the treatment of hepatitis C** means medication mentioned in the table in paragraph 3 of the General Statement for drugs for the treatment of hepatitis C set out in Part 3 of Schedule 4 to the Listing Instrument.

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

- (a) abacavir;
- (b) abacavir with lamivudine;
- (c) abacavir with lamivudine and zidovudine;
- (d) atazanavir;
- (e) atazanavir with cobicistat;
- (f) azithromycin;
- (g) bictegravir with emtricitabine with tenofovir alafenamide;
- (h) darunavir;
- (i) darunavir with cobicistat;
- (j) dolutegravir;
- (k) dolutegravir with abacavir and lamivudine;
- (l) dolutegravir with lamivudine;
- (m) dolutegravir with rilpivirine;
- (n) doxorubicin - pegylated liposomal;
- (o) efavirenz;
- (p) emtricitabine with rilpivirine with tenofovir alafenamide;
- (q) emtricitabine with tenofovir alafenamide;
- (r) enfuvirtide;
- (s) etravirine;
- (t) fosamprenavir;
- (u) ganciclovir;
- (v) lamivudine;
- (w) lamivudine with zidovudine;
- (x) lopinavir with ritonavir;
- (y) maraviroc;

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- (z) nevirapine;
- (za) raltegravir;
- (zb) rifabutin;
- (zc) rilpivirine;
- (zd) ritonavir;
- (ze) saquinavir;
- (zf) tenofovir;
- (zg) tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat;
- (zh) tenofovir with emtricitabine;
- (zi) tenofovir with emtricitabine and efavirenz;
- (zj) tipranavir;
- (zk) valganciclovir;
- (zl) zidovudine.

**medication for the treatment of schizophrenia** means clozapine.

**non-CAR drug** means a highly specialised drug that is not a CAR drug.

**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.

**shelf life**, of a medicine, means the period of time that the medicine can be stored and still be considered safe and effective for use.

**special arrangement supply** has the meaning given by section 13.

## 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;
  - (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 medication for the treatment of hepatitis C;
  - (b) lanreotide, if:
    - (i) the description of its form does not include “Powder for suspension for injection”; and
    - (ii) it is for continuing treatment;
  - (c) octreotide, if:
    - (i) the description of its form includes “Injection (modified release)”; and
    - (ii) it is for continuing treatment.

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

- (5) A person mentioned in column 1 of an item of the following table is an **authorised prescriber** for an HSD pharmaceutical benefit mentioned in column 2 of the item.

<b>Authorised prescribers for certain HSD pharmaceutical benefits</b>		
<b>Item</b>	<b>Column 1 Person</b>	<b>Column 2 HSD pharmaceutical benefit</b>
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

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**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:
- (a) is, or is to be treated as, an eligible person; and
  - (b) is receiving medical treatment by a medical practitioner at or from a public hospital; and
  - (c) is receiving that treatment as:
    - (i) a non-admitted patient of the hospital; or
    - (ii) a day admitted patient of the hospital; or
    - (iii) a patient on discharge from the hospital.

*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 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 at or from a public hospital; and
  - (c) is receiving that treatment as:
    - (i) a non-admitted patient of the hospital; or
    - (ii) a day admitted patient of the hospital; or
    - (iii) 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*

- (3) A person is an ***eligible patient*** for an HSD pharmaceutical benefit that contains eculizumab 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 a public hospital;
  - (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.

*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 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 are community access medications*

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

**Part 1** Preliminary

**Division 2** Supplies of HSD pharmaceutical benefits from hospitals

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**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

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#### 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—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) 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) 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:
- (a) the benefit 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**

### **14 Prescribing of HSD pharmaceutical benefits—authorised prescribers (Act s 88(1) and (1E))**

#### *Medical practitioners*

- (1) For the purposes of subsection 88(1) of the Act applying to a medical practitioner who is an authorised prescriber for an HSD pharmaceutical benefit, the benefit is determined.
- (2) Subsection 9(1A) of the Listing Instrument (which provides for the pharmaceutical benefits for which medical practitioners are authorised to write prescriptions) does not apply to an HSD pharmaceutical benefit other than a medication for the treatment of hepatitis C.

#### *Authorised nurse practitioners*

- (3) For the purposes of subsection 88(1E) of the Act applying to an authorised nurse practitioner who is an authorised prescriber for an HSD pharmaceutical benefit, the benefit is determined.

#### *“Supply only” pharmaceutical benefits*

- (4) Subsections (1) and (3) do not apply to an HSD pharmaceutical benefit mentioned in Part 2 of Schedule 1 to the Listing Instrument (ready-prepared pharmaceutical benefits for supply only).

### **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 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 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 10 of the Listing Instrument.
- (4) This section has effect subject to section 17 (which temporarily modifies the circumstances mentioned in Schedule 3 for circumstances codes for HSD pharmaceutical benefits that are pharmaceutical items described in Schedule 4).

### **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 in which the prescription is written include:
  - (a) Compliance with Authority Required procedures; or

- (b) Compliance with Written Authority Required procedures.
- (2) Sections 11 to 14 of the Listing Instrument apply to the prescription as if:
  - (a) a reference in those provisions to “Part 1 of Schedule 4” or “Schedule 4” were a reference to Schedule 3 to this instrument; and
  - (b) a reference in those provisions to an “authorised prescriber” were a reference to an authorised prescriber within the meaning of this instrument.

### **17 Prescription circumstances—modifications during COVID-19 pandemic (Acts 85(7)(a) and (b))**

- (1) This section affects the circumstances in which a prescription may be written by an authorised prescriber for the supply of an HSD pharmaceutical benefit that is a listed brand of a pharmaceutical item described in Schedule 4 to a person (the *patient*) if the authorised prescriber is satisfied the patient has, in accordance with this instrument, already been supplied with the benefit on the basis of a prescription:
  - (a) written, on or after 1 April 2021, in circumstances determined by subsection 10(1) of the Listing Instrument unaffected by this section; or
  - (b) written, before 1 April 2021, in circumstances determined by subsection 9(1) of the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) unaffected by section 9AA of that instrument.
- (2) For the purposes of subsection 10(1) of the Listing Instrument and subsection 15(2) of this instrument, Part 1 of Schedule 4 to the Listing Instrument and Schedule 3 to this instrument have effect as if each circumstances code for the HSD pharmaceutical benefit:
  - (a) did not mention any circumstance that, having regard to the patient’s situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish in relation to the patient; and
  - (b) mentioned the circumstance that the authorised prescriber keeps a written record of the reason it is not practicable to establish the circumstance described in paragraph (a).
- (3) This section, subsection 15(4) and Schedule 4 to this instrument are repealed at the start of 1 January 2022.

### **18 When medication chart prescriptions not to be written**

#### *HSD pharmaceutical benefits that have CAR drugs*

- (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.

#### *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.

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**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 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
  - (a) 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.

- (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.

- (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.

Section 22

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**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 contain eculizumab**

- (1) If an authorised prescriber for an HSD pharmaceutical benefit that contains eculizumab 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.

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## 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.

<b>Special patient contribution for certain HSD pharmaceutical benefits</b>						
<b>Item</b>	<b>Drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Pack quantity</b>	<b>Claimed price (\$)</b>
1	Lamivudine	Tablet 100 mg	Oral	Zeffix	28	35.30
2	Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valtrex	100	44.64

- (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 Modified application of conditions of approval of approved pharmacists

Section 8 of the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* (PB 70 of 2017) does not apply to a special arrangement supply of an HSD pharmaceutical benefit, once prepared as a final product ready for infusion to a person, if the benefit has a physical, chemical or biological stability restricting its clinically effective shelf life to 8 hours or less.

### 26 Supplies by HSD hospital authorities need not be directly to persons

- (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.
- (2) 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.

Section 28

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## 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.
- (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 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) the amount calculated in accordance with subsection (2) for the remainder of the quantity that is a broken quantity.

##### *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).

Section 30

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

### 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.
- (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;
- (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;
- (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.

*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:

Section 34

- (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 extemporaneously-prepared dispensing fee (within the meaning of the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020* (PB 66 of 2020)); 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, only one dispensing fee is included in the dispensed price for the supply of the benefit.

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 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 (Claims and under co-payment data) Rules 2012* (PB 19 of 2012) 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.

## 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.

#### *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.
- (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.

## Schedule 1 HSD pharmaceutical benefits and related information

### Clause 1

# 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	Tablet 300 mg (as sulfate)	Oral	Ziagen	C4454 C4512		120	5
	Oral solution 20 mg (as sulfate) per mL, 240 mL	Oral	Ziagen	C4454 C4512		8	5
Abacavir with Lamivudine	Tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg	Oral	Abacavir/Lamivudine GH 600/300	C4527 C4528		60	5
	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	ABACAVIR/LAMIVU DINE 600/300 SUN	C4527 C4528		60	5
			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
			Kivexa	C4527 C4528		60	5
Abacavir with Lamivudine and Zidovudine	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	Oral	Trizivir	C4480 C4495		120	5
Abatacept	Powder for I.V. infusion 250 mg	Injection	Orencia	C8627 C8638 C8655 C8688 C8748 C8759		See Schedule 2	See Schedule 2
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Humira	C9384 C9417 C10582 C10583 C10600 C10619		See Schedule 2	See Schedule 2
	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Humira	C9384 C9417 C10582 C10583 C10600 C10619		See Schedule 2	See Schedule 2
	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Humira	C9384 C9417 C10582 C10583 C10600 C10619		See Schedule 2	See Schedule 2
Adefovir	Tablet containing adefovir dipivoxil 10 mg	Oral	APO-Adefovir	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 Mylan	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		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
			Cipla Ambrisentan	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
			PULMORIS	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
			Volibris	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
	Tablet 10 mg	Oral	Ambrisentan Mylan	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
			Cipla Ambrisentan	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
			PULMORIS	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
			Volibris	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11321 C11354		See Schedule 2	See Schedule 2
Anakinra	Injection 100 mg in 0.67 mL single use pre-filled syringe	Injection	Kineret	C5450		28	5

**HSD pharmaceutical benefits and related information**

<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL	Injection	Movapo	C4833 C9561		360	5
	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	Injection	Movapo	C4833 C9561		180	5
	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	C4833 C9561		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
Atazanavir	Capsule 200 mg (as sulfate)	Oral	Atazanavir Mylan	C4454 C4512		120	5
			Reyataz	C4454 C4512		120	5
	Capsule 300 mg (as sulfate)	Oral	Atazanavir Mylan	C4454 C4512		60	5
			Reyataz	C4454 C4512		60	5

**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
Atazanavir with cobicistat	Tablet containing 300 mg atazanavir and 150 mg cobicistat	Oral	Evotaz	C4454 C4512		60	5
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Accord	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
			AZACITIDINE DR.REDDY'S	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
			Azacitidine Juno	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
			Azacitidine-Teva	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
			Azadine	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
			Celazadine	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
			Vidaza	C6132 C6143 C6144 C6177 C6186 C6199		See Schedule 2	See Schedule 2
Azithromycin	Tablet 600 mg (as dihydrate)	Oral	Zithromax	C6356 C9604		16	5
Baclofen	Intrathecal injection 10 mg in 5 mL	Injection	Bacthecal	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

**HSD pharmaceutical benefits and related information**

Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	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	C9887 C10264 C10281 C10314		See Schedule 2	See Schedule 2
	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection	Fasenra	C9887 C10264 C10281 C10314		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	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan Cipla	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			BOSENTAN DR.REDDY'S	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		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
			Bosentan Mylan	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan RBX	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan Sandoz	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			BOSLEER	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Tracleer	C10228 C10238 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
	Tablet 125 mg (as monohydrate)	Oral	Bosentan APO	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2

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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
			Bosentan Cipla	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			BOSENTAN DR.REDDY'S	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan GH	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan Mylan	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan RBX	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Bosentan Sandoz	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			BOSLEER	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
			Tracleer	C10228 C10924 C10945 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Ciclosporin	Capsule 10 mg	Oral	Neoral 10	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
	Capsule 25 mg	Oral	Cyclosporin Sandoz	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
			Neoral 25	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
	Capsule 50 mg	Oral	Cyclosporin Sandoz	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
			Neoral 50	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
	Capsule 100 mg	Oral	Cyclosporin Sandoz	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
			Neoral 100	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5
	Oral liquid 100 mg per mL, 50 mL	Oral	Neoral	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		4	5



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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Solution concentrate for I.V. infusion 50 mg in 1 mL	Injection	Sandimmun	C6628 C9831		10	0
Cinacalcet	Tablet 30 mg (as hydrochloride)	Oral	Pharmacor Cinacalcet	C10063 C10067 C10073		56	5
	Tablet 60 mg (as hydrochloride)	Oral	Pharmacor Cinacalcet	C10063 C10067 C10073		56	5
	Tablet 90 mg (as hydrochloride)	Oral	Pharmacor Cinacalcet	C10063 C10067 C10073		56	5
Clozapine	Tablet 25 mg	Oral	Clopine 25	C4998 C5015 C9490		200	0
			Clozaril 25	C4998 C5015 C9490		200	0
	Tablet 50 mg	Oral	Clopine 50	C4998 C5015 C9490		200	0
	Tablet 100 mg	Oral	Clopine 100	C4998 C5015 C9490		200	0
			Clozaril 100	C4998 C5015 C9490		200	0
	Tablet 200 mg	Oral	Clopine 200	C4998 C5015 C9490		200	0
	Oral liquid 50 mg per mL, 100 mL	Oral	Clopine Suspension	C4998 C5015 C9490		1	0
			Versacloz	C4998 C5015 C9490		1	0
Darbepoetin Alfa	Injection 10 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 20 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 20 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	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 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 50 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 60 micrograms in 0.3 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 80 micrograms in 0.4 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 100 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	C6294 C9688		8	5
	Injection 100 micrograms in 0.5 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

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
	Injection 150 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	C6294 C9688		8	5
Darunavir	Tablet 150 mg (as ethanolate)	Oral	Prezista	C5094		240	5
	Tablet 600 mg (as ethanolate)	Oral	Prezista	C5094		120	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
Deferasirox	Tablet 90 mg	Oral	Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
				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
	Tablet 180 mg	Oral	Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
				C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
	Tablet 360 mg	Oral	Jadenu	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2
				C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5
Deferiprone	Tablet 500 mg	Oral	Ferriprox	C6403 C6448 C9228 C9286		300	5
	Tablet 1000 mg	Oral	Ferriprox	C6403 C6448 C9590 C9623		300	5
	Oral solution 100 mg per mL, 250 mL	Oral	Ferriprox	C6403 C6448 C9228 C9286		5	5

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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
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
Dolutegravir	Tablet 50mg (as sodium)	Oral	Tivicay	C4454 C4512		60	5
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

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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	C6626 C6637 C6642 C6668 C6686 C6687 C6688		See Schedule 2	See Schedule 2
Efavirenz	Tablet 200 mg	Oral	Stocrin	C4454 C4512		180	5
	Tablet 600 mg	Oral	Stocrin	C4454 C4512		60	5
	Oral solution 30 mg per mL, 180 mL	Oral	Stocrin	C4454 C4512		7	5
Eltrombopag	Tablet 25 mg (as olamine)	Oral	Revolade	C11199 C11202 C11244 C11262 C11263		See Schedule 2	See Schedule 2
	Tablet 50 mg (as olamine)	Oral	Revolade	C11199 C11202 C11244 C11262 C11263		See Schedule 2	See Schedule 2
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
Enfuvirtide	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	Injection	Fuzeon	C5014		2	5

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Entecavir	Tablet 0.5 mg (as monohydrate)	Oral	Baraclude	C4993 C5036		60	5
			ENTAC	C4993 C5036		60	5
			Entecavir Amneal	C4993 C5036		60	5
			ENTECAVIR APO	C4993 C5036		60	5
			Entecavir APOTEX	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
			ENTECLUDE	C4993 C5036		60	5
	Tablet 1 mg (as monohydrate)	Oral	Baraclude	C5037 C5044		60	5
			ENTAC	C5037 C5044		60	5
			Entecavir Amneal	C5037 C5044		60	5
			ENTECAVIR APO	C5037 C5044		60	5
			Entecavir APOTEX	C5037 C5044		60	5
			Entecavir GH	C5037 C5044		60	5
			Entecavir Mylan	C5037 C5044		60	5
			ENTECAVIR RBX	C5037 C5044		60	5
			Entecavir Sandoz	C5037 C5044		60	5
			ENTECLUDE	C5037 C5044		60	5

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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
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
	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



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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
	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
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

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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	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	EPOPROSTENOL SUN	C10241 C11322 C11323 C11325 C11329 C11330 C11345 C11356		See Schedule 2	See Schedule 2	
			Veletri	C10241 C11322 C11323 C11325 C11329 C11330 C11345 C11356		See Schedule 2	See Schedule 2	
	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection	Flolan		C10241 C11322 C11323 C11325 C11329 C11330 C11345 C11356		See Schedule 2	See Schedule 2
	Powder for I.V. infusion 1.5 mg (as sodium)	Injection		EPOPROSTENOL SUN	C10241 C11322 C11323 C11325 C11329 C11330 C11345 C11356		See Schedule 2	See Schedule 2
				Veletri	C10241 C11322 C11323 C11325 C11329 C11330 C11345 C11356		See Schedule 2	See Schedule 2
Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection	Flolan		C10241 C11322 C11323 C11325 C11329 C11330 C11345 C11356		See Schedule 2	See Schedule 2	

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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	C9384 C9417 C10548 C10578 C10579 C10599		See Schedule 2	See Schedule 2
	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	C9384 C9417 C10548 C10578 C10579 C10599		See Schedule 2	See Schedule 2
	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	C9384 C9417 C10548 C10578 C10579 C10599		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
	Tablet 0.5 mg	Oral	Certican	C5554 C5795 C9691 C9693		120	5
	Tablet 0.75 mg	Oral	Certican	C5554 C5795 C9691 C9693		240	5
	Tablet 1 mg	Oral	Certican	C5554 C5795 C9691 C9693		240	5
Filgrastim	Injection 120 micrograms in 0.2 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
	Injection 300 micrograms in 0.5 mL single-use pre-filled syringe	Injection	Neupogen	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
			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
	Injection 300 micrograms in 1 mL	Injection	Neupogen	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
	Injection 480 micrograms in 0.5 mL single-use pre-filled syringe	Injection	Neupogen	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
			Nivestim	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
			Zarzio	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11
Fosamprenavir	Tablet 700 mg (as calcium)	Oral	Telzir	C4454 C4512		120	5
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
Grazoprevir with elbasvir	Tablet containing grazoprevir 100 mg with elbasvir 50 mg	Oral	Zepatier	C5969 C6625	P5969	28	2
				C5969 C6625	P6625	28	3

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
Ibandronic acid	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	Injection	Bondronat	C5291 C9333		1	11
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation	Ventavis	C10229 C11322 C11323 C11325 C11343 C11345 C11356 C11365		See Schedule 2	See Schedule 2
Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	C4524 C7777 C8296 C8644 C8645 C8646 C8715 C8743 C8744 C8745 C8755 C8800 C8844 C8881 C8883 C8886 C8940 C8941 C8962 C8983 C9065 C9067 C9068 C9110 C9111 C9169 C9188 C9191 C9400 C9401 C9402 C9472 C9481 C9487 C9558 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9675 C9676 C9677 C9719 C9721 C9731 C9732 C9733 C9751 C9752 C9754 C9756 C9759 C9775 C9776 C9778 C9779 C9781 C9783 C9785 C9787 C9788 C9799 C9800 C9803 C9806 C9877 C9900 C9975 C9994 C11094 C11095 C11111 C11112 C11127		See Schedule 2	See Schedule 2

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
				C11128 C11129 C11158 C11159			
			Remicade	C4524 C7777 C8296 C8644 C8645 C8646 C8715 C8743 C8744 C8745 C8800 C8881 C8883 C8886 C8941 C8962 C8983 C9065 C9067 C9068 C9110 C9111 C9169 C9191 C9400 C9401 C9402 C9487 C9558 C9559 C9587 C9632 C9669 C9675 C9676 C9677 C9719 C9721 C9751 C9752 C9754 C9756 C9759 C9776 C9778 C9779 C9781 C9783 C9788 C9799 C9800 C9803 C9877 C9900 C9994 C11094 C11095 C11111 C11112 C11127 C11128 C11129 C11158 C11159		See Schedule 2	See Schedule 2
			Renflexis	C4524 C7777 C8296 C8644 C8645 C8646 C8715 C8743 C8744 C8745 C8755 C8800 C8844 C8881 C8883 C8886 C8940 C8941 C8962 C8983 C9065 C9067 C9068 C9110 C9111 C9169 C9188 C9191		See Schedule 2	See Schedule 2

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				C9400 C9401 C9402 C9472 C9481 C9487 C9558 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9675 C9676 C9677 C9719 C9721 C9731 C9732 C9733 C9751 C9752 C9754 C9756 C9759 C9775 C9776 C9778 C9779 C9781 C9783 C9785 C9787 C9788 C9799 C9800 C9803 C9806 C9877 C9900 C9975 C9994 C11094 C11095 C11111 C11112 C11127 C11128 C11129 C11158 C11159				
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	C4993 C5036 C5042 C9259		30	5	
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	C4993 C5036 C5042 C9259		30	5	



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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
Interferon Gamma-1b	Injection 2,000,000 I.U. in 0.5 mL	Injection	Imukin	C6222 C9639		12	11
Ivacaftor	Sachet containing granules 50 mg	Oral	Kalydeco	C9889 C9890		See Schedule 2	See Schedule 2
	Sachet containing granules 75 mg	Oral	Kalydeco	C9889 C9890		See Schedule 2	See Schedule 2
	Tablet 150 mg	Oral	Kalydeco	C9889 C9890		See Schedule 2	See Schedule 2
Lamivudine	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
			Lamivudine Alphapharm	C4454 C4512		60	5
	Oral solution 10 mg per mL, 240 mL	Oral	3TC	C4454 C4512		8	5
Lamivudine with Zidovudine	Tablet 150 mg-300 mg	Oral	Combivir	C4454 C4512		120	5
			Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	C4454 C4512		120	5

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Lanreotide	Injection 60 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	C4575 C7025 C7509 C7532 C9260 C9261		2	5
	Injection 90 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	C4575 C7025 C7509 C7532 C9260 C9261		2	5
	Injection 120 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	C4575 C7025 C7509 C7532 C9260 C9261 C10061 C10075 C10077		2	5
	Powder for suspension for injection 30 mg (as acetate) with diluent	Injection	Somatuline LA	C7042 C9225		2	11
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
Ledipasvir with sofosbuvir	Tablet containing 90 mg ledipasvir with 400 mg sofosbuvir	Oral	Harvoni	C5944 C5969 C5972	P5944	28	1
				C5944 C5969 C5972	P5969	28	2
				C5944 C5969 C5972	P5972	28	5
Lenalidomide	Capsule 5 mg	Oral	Revlimid	C4282 C4287 C10334 C10335 C10349 C10350 C10373 C10427 C10428 C10429		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	Revlimid	C10452 C10453 C4282 C4287 C10334 C10335 C10349 C10350 C10373 C10427 C10428 C10429 C10452 C10453		See Schedule 2	See Schedule 2
	Capsule 15 mg	Oral	Revlimid	C10334 C10335 C10349 C10350 C10373 C10427 C10428 C10429 C10452 C10453		See Schedule 2	See Schedule 2
	Capsule 25 mg	Oral	Revlimid	C10349 C10350 C10373 C10427 C10428 C10429 C10452 C10453		See Schedule 2	See Schedule 2
Lenograstim	Powder for injection 13,400,000 I.U. (105 micrograms)	Injection	Granocyte 13	C6502 C6507 C6516 C6522 C6523 C6532 C6535 C6634 C6644 C6653 C6654 C6657 C6673 C6682 C9226 C9227 C9229 C9230 C9231 C9263 C9264 C9265 C9266 C9314 C9324 C9325 C9326 C9327		20	11
	Powder for injection 33,600,000 I.U. (263 micrograms)	Injection	Granocyte 34	C6502 C6507 C6516 C6522 C6523 C6532 C6535 C6634 C6644 C6653 C6654 C6657 C6673 C6682 C9226 C9227 C9229 C9230 C9231 C9263 C9264 C9265 C9266 C9314 C9324 C9325 C9326 C9327		20	11

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
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
Lopinavir with Ritonavir	Tablet 100 mg-25 mg	Oral	Kaletra	C4454 C4512		120	5
	Tablet 200 mg-50 mg	Oral	Kaletra	C4454 C4512		240	5
	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	Oral	Kaletra	C4454 C4512		10	5
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral	Orkambi	C10005 C10007		See Schedule 2	See Schedule 2
	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral	Orkambi	C10005 C10007		See Schedule 2	See Schedule 2
	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral	Orkambi	C9891 C9920		See Schedule 2	See Schedule 2
	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral	Orkambi	C9857 C9943		See Schedule 2	See Schedule 2

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Macitentan	Tablet 10 mg	Oral	Opsumit	C10228 C10236 C10285 C11229 C11312 C11313 C11314 C11317 C11321		See Schedule 2	See Schedule 2
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	C9885 C10221 C10222 C10280 C10483 C10484		See Schedule 2	See Schedule 2
	Powder for injection 100 mg	Injection	Nucala	C9885 C10221 C10222 C10280		See Schedule 2	See Schedule 2
Methoxsalen	Solution for blood fraction 20 microgram per mL, 10 mL	Extracorporeal Circulation	Uvadex	C10971 C10985 C10988 C10989	P10988 P10989	1	5
				C10971 C10985 C10988 C10989	P10971 P10985	2	6
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

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	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
	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	C8138 C8177 C8193 C8218		See Schedule 2	See Schedule 2
Mycophenolic Acid	Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid	Oral	Myfortic	C4084 C4095 C9692 C9809		240	5
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	Myfortic	C4084 C4095 C9692 C9809		240	5
	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

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Listed drug	Form	Manner of administration	Brand	Circumstances	Purposes	Maximum quantity	Maximum repeats
			Mycophenolate Sandoz	C5600 C5653 C9689 C9690		600	5
			Pharmacor Mycophenolate 250	C5600 C5653 C9689 C9690		600	5
	Tablet containing mycophenolate mofetil 500 mg	Oral	APO-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 AN	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
	Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL	Oral	CellCept	C5554 C5795 C9691 C9693		2	5
Natalizumab	Solution concentrate for I.V. infusion 300 mg in 15 mL	Injection	Tysabri	C9744 C9818		1	5

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Nevirapine	Tablet 200 mg	Oral	Nevirapine Alphapharm	C4454 C4512		120	5
	Tablet 400 mg (extended release)	Oral	Nevirapine XR APOTEX	C4454 C4526		60	5
			Viramune XR	C4454 C4526		60	5
	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	Oral	Viramune	C4454 C4512		10	5
Nusinersen	Solution for injection 12 mg in 5 mL	Injection	Spinraza	C11049 C11050 C11058		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 MaxRx	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 100 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide MaxRx	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
			Octreotide (SUN)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Sandostatin 0.1	C6369 C6390 C8165 C9232 C9233 C9289		90	11
	Injection 500 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide MaxRx	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Octreotide (SUN)	C6369 C6390 C8165 C9232 C9233 C9289		90	11
			Sandostatin 0.5	C6369 C6390 C8165 C9232 C9233 C9289		90	11
	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	Injection	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	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	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	C9855 C10219 C10223 C10226 C10265 C10279 C10299		See Schedule 2	See Schedule 2

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	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Xolair	C7046 C7055 C9855 C10219 C10223 C10226 C10265 C10279 C10299		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
	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

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Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Fulphila	C7822 C7843 C9235 C9303		1	11
			Neulasta	C7822 C7843 C9235 C9303		1	11
			Pelgraz	C7822 C7843 C9235 C9303		1	11
			Ristempa	C7822 C7843 C9235 C9303		1	11
			Tezmota	C7822 C7843 C9235 C9303		1	11
			Ziextenzo	C7822 C7843 C9235 C9303		1	11
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

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Plerixafor	Injection 24 mg in 1.2 mL	Injection	Mozobil	C4549 C9329		1	1
Pomalidomide	Capsule 3 mg	Oral	Pomalyst	C7791 C7952		See Schedule 2	See Schedule 2
	Capsule 4 mg	Oral	Pomalyst	C7791 C7952		See Schedule 2	See Schedule 2
Raltegravir	Tablet 25 mg (as potassium)	Oral	Isentress	C4274 C4275		360	5
	Tablet 100 mg (as potassium)	Oral	Isentress	C4274 C4275		360	5
	Tablet 400 mg (as potassium)	Oral	Isentress	C4454 C4512		120	5
	Tablet 600 mg (as potassium)	Oral	Isentress HD	C4454 C4512		120	5
Ribavirin	Tablet 400 mg	Oral	Ibavyr	C5957 C5958	P5957	28	2
				C5957 C5958	P5958	28	5
	Tablet 600 mg	Oral	Ibavyr	C5957 C5958	P5957	28	2
				C5957 C5958	P5958	28	5
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	C6645 C6664 C7629 C10231 C10243 C10245		See Schedule 2	See Schedule 2
	Tablet 1 mg	Oral	Adempas	C6645 C6664 C7629 C10231 C10243 C10245		See Schedule 2	See Schedule 2
	Tablet 1.5 mg	Oral	Adempas	C6645 C6664 C7629 C10231 C10243 C10245		See Schedule 2	See Schedule 2
	Tablet 2 mg	Oral	Adempas	C6645 C6664 C7629 C10231 C10243 C10245		See Schedule 2	See Schedule 2

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	Tablet 2.5 mg	Oral	Adempas	C6645 C6664 C7629 C10231 C10243 C10245		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	Mabthera	C7021 C7022 C9344 C9511		See Schedule 2	See Schedule 2
			Riximyo	C7021 C7022 C9336 C9344 C9511 C9539 C9640 C9641		See Schedule 2	See Schedule 2
			Truxima	C7021 C7022 C9336 C9344 C9511 C9539 C9640 C9641		See Schedule 2	See Schedule 2
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	C7021 C7022 C9340 C9344 C9448 C9449 C9450 C9511 C9512		See Schedule 2	See Schedule 2
Riximyo	C7021 C7022 C9336 C9340 C9344 C9446 C9448 C9449 C9450 C9511 C9512 C9539 C9611 C9640 C9641			See Schedule 2	See Schedule 2		
			Truxima	C7021 C7022 C9336 C9340 C9344 C9446 C9448 C9449 C9450 C9511 C9512 C9539 C9611 C9640 C9641		See Schedule 2	See Schedule 2
Romiplostim	Powder for injection 375 micrograms	Injection	Nplate	C11205 C11246 C11266 C11267 C11289		See Schedule 2	See Schedule 2
	Powder for injection 625 micrograms			C11205 C11246 C11266 C11267 C11289		See Schedule 2	See Schedule 2

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Saquinavir	Tablet 500 mg (as mesilate)	Oral	Invirase	C4454 C4512		240	5			
Selexipag	Tablet 200 micrograms	Oral	Uptravi	C11193 C11195 C11241	P11193	60	5			
				C11261	P11195					
	Tablet 400 micrograms	Oral	Uptravi	C11193 C11195 C11241	P11241	140	2			
				C11261	P11261					
				C11193 C11195 C11241		60	5			
				C11193 C11195 C11241		60	5			
				Tablet 800 micrograms	Oral	Uptravi	C11193 C11195 C11241	P11261	60	3
							C11261			
				Tablet 1 mg	Oral	Uptravi	C11193 C11195 C11241	P11193	60	5
							C11193 C11195 C11241	P11195		
C11193 C11195 C11241	P11241									
C11193 C11195 C11241		60	5							
C11193 C11195 C11241		60	5							
C11193 C11195 C11241		60	5							
Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral	Sevelamer Apotex	C5530 C9762		360	5			
			Sevelamer Lupin	C5530 C9762				360	5	
	Tablet containing sevelamer hydrochloride 800 mg	Oral	Renagel	C5530 C9762		360	5			

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Sildenafil	Tablet 20 mg (as citrate)	Oral	APO-Sildenafil PHT	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			Revatio	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			SILDATIO PHT	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			Sildenafil AN PHT 20	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			Sildenafil PHT APOTEX	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			Sildenafil Sandoz PHT 20	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			Sildenafil Sandoz PHT 20	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
Sirolimus	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
	Oral solution 1 mg per mL, 60 mL	Oral	Rapamune	C5795 C9914		2	5

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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
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 APOTEX	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
	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	



**HSD pharmaceutical benefits and related information**

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

**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
Tadalafil	Tablet 20 mg	Oral	Adcirca	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			Tadalca	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
			TADALIS 20	C10228 C10234 C10304 C11229 C11319 C11338 C11340 C11350 C11352		See Schedule 2	See Schedule 2
Teduglutide	Powder for injection 5 mg with diluent	Injection	Revestive	C9515 C9569 C9687 C9740 C9793 C9829		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
			Viread	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2
			Tenofovir APOTEX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5

**HSD pharmaceutical benefits and related information**

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

**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
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	Tenofovir/Emtricitabine 300/200 APOTEX	C6985 C6986		60	5
	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	Oral	Tenofovir Disoproxil Emtricitabine Mylan 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
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 Mylan 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	C9880 C9961 C10064 C10069		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

**HSD pharmaceutical benefits and related information**

<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
Tipranavir	Capsule 250 mg	Oral	Aptivus	C5764		240	5
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Actemra	C8627 C8635 C8636 C8637 C8638 C8709 C9380 C9384 C9386 C9407 C9417 C9494 C9495 C9496 C10532 C10535 C10536 C10541 C10542 C10545 C10567 C10570 C10571 C10616		See Schedule 2	See Schedule 2
	Concentrate for injection 200 mg in 10 mL	Injection	Actemra	C8627 C8635 C8636 C8637 C8638 C8709 C9380 C9384 C9386 C9407 C9417 C9494 C9495 C9496 C10532 C10535 C10536 C10541 C10542 C10545 C10567 C10570 C10571 C10616		See Schedule 2	See Schedule 2
	Concentrate for injection 400 mg in 20 mL	Injection	Actemra	C8627 C8635 C8636 C8637 C8638 C8709 C9380 C9384 C9386 C9407 C9417 C9494 C9495 C9496 C10532 C10535 C10536 C10541 C10542 C10545 C10567 C10570 C10571 C10616		See Schedule 2	See Schedule 2
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection	Stelara	C9655 C9656 C9710		See Schedule 2	See Schedule 2
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	APO-Valaciclovir	C5975 C9267		500	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
			Valaciclovir APOTEX	C5975 C9267		500	2
			Valaciclovir RBX	C5975 C9267		500	2
			Valtrex	C5975 C9267		500	2
Valganciclovir	Tablet 450 mg (as hydrochloride)	Oral	Valcyte	C4980 C4989 C9316		120	5
			Valganciclovir Mylan	C4980 C4989 C9316		120	5
			Valganciclovir Sandoz	C4980 C4989 C9316		120	5
	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	Oral	Valcyte	C4980 C4989 C9316		11	5
Vedolizumab	Powder for injection 300 mg	Injection	Entyvio	C9682 C9683 C9708 C9738 C9739 C9771 C9792 C9796 C9815 C9825		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	APO-Zoledronic Acid	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11

**HSD pharmaceutical benefits and related information**

<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>	<b>Brand</b>	<b>Circumstances</b>	<b>Purposes</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
			DBL Zoledronic Acid	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11
			DEZTRON	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11
			Zometa	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11
	Solution for I.V. infusion 4 mg (as monohydrate) in 100 mL	Injection	DBL Zoledronic Acid	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11

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

### Clause 1

## 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.

<b>Maximum quantity or number of units, and maximum number of repeats</b>			
<b>Listed drug</b>	<b>Circumstances</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
Abatacept	C8638, C8688	1 dose	Sufficient for treatment for 16 weeks
	C8759, C8748	1 dose	4
	C8627, C8655	1 dose	Sufficient for treatment for 24 weeks
Adalimumab	C9417, C10582, C10583, C10619	2 doses	3
	C9384, C10600	2 doses	5
Ambrisentan	C10228, C10236, C10285, C11007, C11008, C11010, C11024, C11037	Sufficient for treatment for 1 month	5
Azacitidine	C6132, C6143, C6177	14 units	2
	C6144, C6186, C6199	14 units	5
Bosentan	C10228, C10924, C10945, C11004, C11022, C11023, C11036, C11044, C11064	Sufficient for treatment for 1 month	5
	C10238	Sufficient for treatment for 1 month	0
Eltrombopag	C6724, C6725, C6738, C6739, C6790	Sufficient for treatment for 4 weeks	5
Epoprostenol	C10228, C10240, C20241	Sufficient for treatment for 1 month	5
Etanercept	C9417, C10548, C10578, C10599	Sufficient for treatment for 4 weeks	3
	C9384, C10579	Sufficient for treatment for 4 weeks	5
Iloprost	C10228, C10229, C10284	Sufficient for treatment for 1	5



<b>Maximum quantity or number of units, and maximum number of repeats</b>			
<b>Listed drug</b>	<b>Circumstances</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
		month	
Infliximab	C9400, C9401, C9402, C9558, C9559, C8800, C9587, C8801, C8885, C8983, C9110, C8886, C9111, C9169, C9191, C9877, C9994	1 dose of 5 mg per kg of patient weight	3
	C8645, C8715, C8646, C8743, C8886, C9111	1 dose of 3 mg per kg of patient weight	3
	C8644, C8744, C7777, C8296, C8745, C9068, C9487, C9669, C8755, C8844, C8940, C9188, C9472, C9481, C9584, C9602, C9621, C9668, C9975	1 dose of 3 mg per kg of patient weight	2
	C8881, C8883, C8941, C8962, C9065, C9067, C7777, C8296, C8745, C9068, C9487, C9669, C9676, C9677, C9719, C9721, C9751, C9752, C9754, C9759, C9779, C9783, C9788, C9806, C4524, C9799, C9803, C9900, C9675, C9756, C9776, C9778, C9781, C9800, C9731, C9733, C9732, C9775, C9785, C9787	1 dose of 5 mg per kg of patient weight	2
Lenalidomide	C10452, C10453	14 Tablets	3
	C4287, C4282, C10428	21 Tablets	3
	C10429	21 Tablets	1
	C10349, C10350, C10373, C10427	21 Tablets	5
	C10334, C10335	28 Tablets	2
Nusinersen	C11049	1 dose	0
	C11050, C11058	1 dose	3
Omalizumab	C7055	2	2
	C7046	2	5
	C10279, C10226	1	5
	C10265, C10223	1	6
	C10219, C10299, C9855	1	7
Pasireotide	C9088, C9089	2	5
Pegvisomant	C7087, C9041	1	5
Riociguat	C6664	Sufficient for treatment for 1 month	3
	C10243, C10245	Sufficient for treatment for 1 month	4
	C6645, C10231, C7629	Sufficient for treatment for 1 month	5
Rituximab	C7021, C7022, C9344, C9511, C9512, C9448, C9449, C9450, C9340	2 doses	Sufficient for treatment for 4 weeks
	C9446, C9611	2 doses	1

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

## Clause 1

<b>Maximum quantity or number of units, and maximum number of repeats</b>			
<b>Listed drug</b>	<b>Circumstances</b>	<b>Maximum quantity</b>	<b>Maximum repeats</b>
	C9336, C9539, C9641, C9640	3 doses	5
Romiplostim	C11205, C11266	1 dose	4
	C11267, C11289, C11246	1 dose	5
Sildenafil	C10228, C11012, C11020, C10998, C11045, C11032, C10304, C10234	Sufficient for treatment for 1 month	5
Tadalafil	C10228, C11012, C11020, C10998, C11045, C11032, C10304, C10234	Sufficient for treatment for 1 month	5
Tocilizumab	C8627, C8635, C8636, C8637, C8638, C8709, C9495, C10536, C10542, C9407, C9494, C9496, C10532, C10535, C10541, C10545, C10567, C10616, C9386, C9417, C10570, C9380, C10571	1 dose	5
Ustekinumab	C9655, C9656, C9710	4 vials - 130 mg each	0
Vedolizumab	C9682, C9683, C9708, C9739, C9792, C9796, C9815, C9825	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
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 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 4528
Abacavir with Lamivudine and Zidovudine	C4480		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Authority Required procedures - Streamlined Authority Code 4480

**Schedule 3** Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C4495		HIV infection Initial Patient must be antiretroviral treatment naïve; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Authority Required procedures - Streamlined Authority Code 4495
Abatacept	C8627		Severe active rheumatoid 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
	C8638		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
	C8655		Severe active rheumatoid arthritis 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; 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 aged 18 years or older. 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 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. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. 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 provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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. 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>	
	C8688		<p>Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement 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 , or ceased to respond to, PBS-subsidised biological medicine</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 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; or (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 aged 18 years or older.                      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.                      The authority application must be made in writing and must include:                      (1) a completed authority prescription form(s); and                      (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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 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.                      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>	
	C8748		<p>Severe active rheumatoid arthritis                      Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).</p>	<p>Compliance with Written                      Authority Required procedures</p>

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 prior PBS-subsidised treatment with a 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 , or 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 aged 18 years or older.            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 has received PBS-subsidised treatment with this drug and who wishes to re-commence 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. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.            To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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 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.            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.            Up to a maximum of 4 repeats will be authorised.            The authority application must be made in writing and must include:</p>	

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>(1) a completed authority prescription form(s); and                      (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      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.                      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>	
	C8759		<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 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                      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                      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 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; 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 aged 18 years or older.                      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>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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.</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 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) 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 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>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>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(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>	

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			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. 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	C9384		Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply 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 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
	C9417		Severe active juvenile idiopathic arthritis 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 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
	C10582		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	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 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>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 sufficient for two doses. 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>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 and submitted 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 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. 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>	
	C10583		Severe active juvenile idiopathic arthritis	Compliance with Written

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			<p>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; or (ii) 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 provided 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.                      The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:                      (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:                      (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 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.                      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.                      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 sufficient for two doses.                      Up to a maximum of 3 repeats will be authorised.</p>	<p>Authority Required procedures</p>

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			<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 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>	
	C10600		<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.</p> <p>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).</p> <p>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 submitted with the initial treatment application.</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 injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. 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 no later than 4 weeks from the date of completion of treatment.</p>	Compliance with Written Authority Required procedures

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			<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 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. 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>	
	C10619		<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> <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; 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>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>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 sufficient for two doses. Up to a maximum of 3 repeats will be authorised.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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>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>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 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>	
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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4490
	C4510		<p>Chronic hepatitis B infection</p> <p>Patient must have cirrhosis; AND</p> <p>Patient must have failed antihepadnaviral therapy; AND</p> <p>Patient must have detectable HBV DNA.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4510
Alemtuzumab	C6847	P6847	<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>Patient must not receive more than one PBS-subsidised treatment per year; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6847

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			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.	
	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
	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



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Ambrisentan	C10228		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10236		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10285		<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</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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>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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11229		Pulmonary arterial hypertension (PAH)	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag</p> <p>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</p> <p>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').</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. 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. 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>	Required procedures
	C11312		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (starting dual therapy in an untreated patient for the first time)</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.</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>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>	Compliance with Written Authority Required procedures

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			<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:                      (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>Applications for authorisation must be in writing and must include:                      (1) a completed authority prescription form; and                      (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:                      (i) RHC composite assessment; and                      (ii) ECHO composite assessment; and                      (iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:                      (1) RHC plus ECHO composite assessments;                      (2) RHC composite assessment plus 6MWT;                      (3) RHC composite assessment only.</p> <p>In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:                      (1) ECHO composite assessment plus 6MWT;                      (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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11313		<p>Pulmonary arterial hypertension (PAH)                      Continuing treatment (dual therapy)                      Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; AND                      The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>antagonist, (ii) one phosphodiesterase-5 inhibitor. 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 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. 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>	
	C11314		<p>Pulmonary arterial hypertension (PAH) Initial 2 (starting dual therapy in a treated patient for the first time) The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated; 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. 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; a prostanoid is one of: (f) epoprostenol, (g) iloprost. 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 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
	C11321		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change)</p>	Compliance with Authority Required procedures

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			<p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor. 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. 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>	
	C11354		<p>Pulmonary arterial hypertension (PAH) Grandfathered patient (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 December 2020; AND Patient must have documented WHO Functional Class III PAH or WHO Functional 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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. 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. 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. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>(iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. 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>	
Anakinra	C5450		<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5450
Apomorphine	C4833		<p>Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4833
	C9561		<p>Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9561
	C10830		<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10830

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	C10863		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 10863
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
Azacitidine	C6132		Chronic Myelomonocytic Leukaemia Initial treatment The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and (d) a copy of the full blood examination report; and (e) a signed patient acknowledgement. No more than 3 cycles will be authorised.	Compliance with Written Authority Required procedures
	C6143		Acute Myeloid Leukaemia Initial treatment The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid	Compliance with Written Authority Required procedures



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			leukaemia; and (d) a copy of the full blood examination report; and (e) a signed patient acknowledgement. No more than 3 cycles will be authorised.	
	C6144		Chronic Myelomonocytic Leukaemia Continuing treatment The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
	C6177		Myelodysplastic syndrome Initial treatment 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.	Compliance with Written Authority Required procedures

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			The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (d) a copy of the full blood examination report; and (e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and (f) a signed patient acknowledgment form. No more than 3 cycles will be authorised.	
	C6186		Acute Myeloid Leukaemia Continuing treatment The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
	C6199		Myelodysplastic syndrome Continuing treatment 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); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
Azithromycin	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
	C9604		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 9604
Baclofen	C6911		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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 Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined 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

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	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	C9887		Uncontrolled severe eosinophilic asthma Balance of supply Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must 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 Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 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 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 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.	Compliance with Authority Required procedures
	C10264		Uncontrolled severe eosinophilic asthma	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Initial treatment - Initial 2 (Change of treatment)            Must be treated by a respiratory physician, clinical immunologist, allergist or 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            Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND            Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND            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            Patient must have had a blood eosinophil count greater than or equal to 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            Patient must have had a blood eosinophil count greater than or equal to 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            Patient must not receive more than 32 weeks of treatment under this restriction; AND            The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.            Patient must be aged 12 years or older.            The authority application must be made in writing and must include:            (a) a completed authority prescription form; and            (b) a completed Severe Eosinophilic Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:            (i) 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            (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and            (iii) eosinophil count and date; and            (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and            (v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).            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.            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>	Authority Required procedures

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			<p>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, 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 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:                      A respiratory physician; and                      A pharmacist, nurse or asthma educator.</p>	
	C10281		<p>Uncontrolled severe eosinophilic asthma                      Continuing treatment                      Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.                      Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug 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 severe asthma; AND                      Patient must not receive more than 24 weeks of treatment under this restriction.                      Patient must be aged 12 years or older.                      An adequate response to this biological medicine is defined as:                      (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,                      OR                      (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.                      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 at around 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.                      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 submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.                      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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes:</p> <p>(i) details of maintenance oral corticosteroid dose; or</p> <p>(ii) a completed Asthma Control Questionnaire (ACQ-5) score.</p>	
	C10314		<p>Uncontrolled severe eosinophilic 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 respiratory physician, clinical immunologist, allergist or 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 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 by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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; AND</p> <p>Patient must have a duration of asthma of at least 1 year; AND</p> <p>Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR</p> <p>Patient must have blood eosinophil count greater than or equal to 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; AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must not receive more than 32 weeks of treatment under this restriction; AND                      The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.                      Patient must be aged 12 years or older.                      Optimised asthma therapy includes:                      (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;                      AND                      (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.                      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.                      The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:                      (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month,                      AND                      (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.                      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.                      This assessment, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.                      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.                      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 3 biological medicines within the same treatment cycle.                      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.                      There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.                      A multidisciplinary severe asthma clinic team comprises of:</p>	



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>A respiratory physician; and A pharmacist, nurse or asthma educator.</p> <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> <p>(a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:</p> <p>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the eosinophil count and date; and (iv) Asthma Control Questionnaire (ACQ-5) score.</p>	
Bictegravir with emtricitabine with tenofovir alafenamide	C4470		<p>HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		<p>HIV infection Initial Patient must be antiretroviral treatment naive.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Bosentan	C10228		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10238		<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. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.</p>	Compliance with Authority Required procedures

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			Treatment beyond 1 month will not be approved.	
	C10924		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. 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>	Compliance with Authority Required procedures
	C10945		<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 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium,</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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>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>Applications for authorisation must be in writing and must include:</p> <p>(1) two completed authority prescription forms; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 months old at the time of application.</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</p>	

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			a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	
	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 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
	C11312		<p>Pulmonary arterial hypertension (PAH)                      Initial 1 (starting dual therapy in an untreated patient for the first time)                      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.</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 physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11313		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment (dual therapy)</p> <p>Patient must have received PBS-subsidised dual therapy through one of the following treatment phase</p>	Compliance with Authority Required procedures

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			<p>restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</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>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>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>	
	C11314		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (starting dual therapy in a treated patient for the first time)</p> <p>The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR</p> <p>The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated;</p> <p>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 endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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,</p>	Compliance with Authority Required procedures

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			based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C11317		<p>Pulmonary arterial hypertension (PAH) Grandfathered patient (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020; AND Patient must have documented WHO Functional Class III PAH or WHO Functional 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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. 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. 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. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p>	Compliance with Written Authority Required procedures

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			<p>(1) ECHO composite assessment plus 6MWT;                      (2) ECHO composite assessment only.                      Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.                      Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.                      A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.                      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>	
	C11321		<p>Pulmonary arterial hypertension (PAH)                      Initial 3 (dual therapy - change)                      Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND                      The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.                      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.                      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
Ciclosporin	C6628		<p>Management of transplant rejection                      The treatment must be used by organ or tissue transplant recipients.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6628
	C6631		<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6631



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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
	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
	C6676		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 dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6676
	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

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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
	C9763		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 dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9763
	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
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	Compliance with Authority Required procedures - Streamlined Authority Code 10067

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	
	C10073		Secondary hyperparathyroidism 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.	Compliance with Authority Required procedures
Clozapine	C4998		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.	Compliance with Authority Required procedures - Streamlined Authority Code 4998
	C5015		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.	Compliance with Authority Required procedures - Streamlined Authority Code 5015

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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 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	Compliance with Authority Required procedures - Streamlined Authority Code 5094

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			treatment-limiting toxicity.	
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
	C10324		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.	Compliance with Authority Required procedures - Streamlined Authority Code 10324

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
Deferasirox	C7374	P7374	Chronic iron overload Initial treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia.	Compliance with Authority Required procedures
	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 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 9258

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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
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
Dolutegravir	C4454		HIV infection	Compliance with Authority

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			Continuing Patient must have previously received PBS subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	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
Dolutegravir with abacavir and lamivudine	C9981		HIV infection Initial treatment Patient must be antiretroviral treatment naïve.	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 naïve; 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 conventional medicines; OR Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath	Compliance with Authority Required procedures - Streamlined Authority Code 5634



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			nitrogen washout and failure to respond to conventional therapy. Patient must be less than 5 years of age. 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. 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.	
	C5635		Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. 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.	Compliance with Authority Required procedures - Streamlined Authority Code 5635
	C5740		Cystic fibrosis Patient must be 5 years of age or older. 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 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.	Compliance with Authority Required procedures - Streamlined Authority Code 5740
	C9591		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 conventional medicines; OR	Compliance with Authority Required procedures - Streamlined Authority Code 9591

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			<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>	
	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>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9592</p>
	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 (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 possibility of harm from unnecessary use.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9624</p>
Doxorubicin - Pegylated Liposomal	C6234		<p>Kaposi sarcoma</p> <p>The condition must be AIDS-related; AND</p> <p>Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND</p> <p>The condition must include extensive mucocutaneous involvement.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 6234</p>
	C6274		<p>Kaposi sarcoma</p>	<p>Compliance with Authority</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	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
Eculizumab	C6626	P6626	Atypical haemolytic uraemic syndrome (aHUS) Initial treatment Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND 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 $150 \mu\text{mol/L}$ ; AND 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 Patient must have clinical features of active organ damage or impairment; AND Patient must not receive more than 4 weeks of treatment under this restriction. Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. Evidence of active and progressing TMA is defined by the following: (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	Compliance with Written Authority Required procedures

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			<p>impairment is defined as below:</p> <p>(a) kidney impairment as demonstrated by one of the following:</p> <p>(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or</p> <p>(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</p> <p>(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or</p> <p>(iv) a renal biopsy consistent with aHUS;</p> <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 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.</p> <p>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:</p> <p>(1) A completed authority prescription form; and</p> <p>(2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and</p> <p>(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and</p> <p>(4) A detailed cover letter from the prescriber; and</p> <p>(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and</p> <p>(6) A measurement of body weight at the time of application; and</p> <p>(7) 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; and</p> <p>(8) 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 1-2 weeks following the last plasma</p>	

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			<p>exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, underInitial treatment 1-balance of supply; and</p> <p>(9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and</p> <p>(10) 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 one month of application; and</p> <p>(11) 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>	
	C6637	P6637	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Extended initial treatment - Assessment phase</p> <p>Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition; AND</p> <p>Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition; AND</p> <p>Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition; AND</p> <p>Patient must not receive more than 56 weeks of treatment under this restriction.</p> <p>Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND</p> <p>(2) One of the following:</p> <p>a) An increase in eGFR of &gt; 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab 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.</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</p>	Compliance with Written Authority Required procedures

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			<p>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 PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.</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:</p> <p>(1) A completed authority prescription form; and</p> <p>(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and</p> <p>(3) A detailed cover letter from the prescriber; and</p> <p>(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and</p> <p>(5) A measurement of body weight at the time of application; and</p> <p>(6) An identified genetic mutation, if applicable; and</p> <p>(7) A family history of aHUS, if applicable; and</p> <p>(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and</p> <p>(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and</p> <p>(10) An inclusion of the individual consequences of recurrent disease, if applicable; and</p> <p>(11) 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; and</p> <p>(12) 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; and</p> <p>(13) 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>	

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	C6642	P6642	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Initial treatment - Balance of Supply</p> <p>Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.</p> <p>Patient must have received PBS-subsidised initial supply of eculizumab for this condition; AND</p> <p>Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND</p> <p>Patient must not receive more than 20 weeks supply under this restriction.</p> <p>ADAMTS-13 activity result must have been submitted to the Department of Human Services. 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 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services 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 two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p>	Compliance with Written Authority Required procedures
	C6668	P6668	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Continuing treatment</p> <p>Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition; AND</p> <p>Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition; AND</p> <p>Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab 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 paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND</p> <p>(2) One of the following:</p> <p>a) An increase in eGFR of &gt; 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or</p> <p>b) an eGFR within +/- 25% from baseline; or</p>	Compliance with Written Authority Required procedures

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			<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.</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 PBS-subsidised eculizumab 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:</p> <p>(1) A completed authority prescription form; and</p> <p>(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and</p> <p>(3) A detailed cover letter from the prescriber; and</p> <p>(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and</p> <p>(5) A measurement of body weight at the time of application; and</p> <p>(6) An identified genetic mutation, if applicable; and</p> <p>(7) A family history of aHUS, if applicable; and</p> <p>(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and</p> <p>(9) A history of kidney transplant if applicable (especially if required due to aHUS); and</p> <p>(10) An inclusion of the individual consequences of recurrent disease, if applicable; and</p> <p>(11) 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; and</p> <p>(12) 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; and</p> <p>(13) 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</p>	



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			<p>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>	
	C6686	P6686	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Extended Continuing treatment</p> <p>Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition; AND</p> <p>Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND</p> <p>Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition; AND</p> <p>Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction &lt; 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 eculizumab; 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 paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND</p> <p>(2) One of the following:</p> <p>a) An increase in eGFR of &gt; 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab 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</p>	Compliance with Written Authority Required procedures

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			<p>failure. 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 PBS-subsidised eculizumab 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:</p> <p>(1) A completed authority prescription form; and</p> <p>(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and</p> <p>(3) A detailed cover letter from the prescriber; and</p> <p>(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and</p> <p>(5) A measurement of body weight at the time of application; and</p> <p>(6) An identified genetic mutation, if applicable; and</p> <p>(7) A family history of aHUS, if applicable; and</p> <p>(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and</p> <p>(9) A history of kidney transplant, if applicable (especially if required due to aHUS); and</p> <p>(10) An inclusion of the individual consequences of recurrent disease; and</p> <p>(11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and</p> <p>(12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and</p> <p>(13) 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; and</p> <p>(14) 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</p>	

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			be deemed to have failed to respond to treatment with eculizumab.	
	C6687	P6687	<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; AND</p> <p>Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition; AND</p> <p>Patient must have the following clinical conditions:(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 &lt;150 x 10<sup>9</sup>/L);OR(iii) TMA-related organ impairment including on recent biopsy; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction.</p> <p>Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND</p> <p>(2) One of the following:</p> <p>a) An increase in eGFR of &gt; 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab 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. 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 PBS-subsidised eculizumab 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>	Compliance with Written Authority Required procedures

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			<p>The authority application must be in writing and must include:</p> <ul style="list-style-type: none"> <li>(1) A completed authority prescription form(s); and</li> <li>(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and</li> <li>(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and</li> <li>(4) A detailed cover letter from the prescriber; and</li> <li>(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and</li> <li>(6) A measurement of body weight at the time of application, and</li> <li>(7) An identified genetic mutation, if applicable; and</li> <li>(8) A family history of aHUS if applicable; and</li> <li>(9) A history of multiple episodes of aHUS following the treatment break, if applicable; and</li> <li>(10) A history of kidney transplant if applicable (especially if required due to aHUS); and</li> <li>(11) An inclusion of the individual consequences of recurrent disease; and</li> <li>(12) 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;</li> <li>(13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and</li> <li>(14) 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; and</li> <li>(15) 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.</li> </ul> <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>	
	C6688	P6688	<p>Atypical haemolytic uraemic syndrome (aHUS) Continuing recommencement of treatment Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition; AND Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition; AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab 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 paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.</p> <p>A treatment response is defined as:</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND</p> <p>(2) One of the following:</p> <p>a) An increase in eGFR of &gt; 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab 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. 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 PBS-subsidised eculizumab 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:</p> <p>(1) A completed authority prescription form; and</p> <p>(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and</p> <p>(3) A detailed cover letter from the prescriber; and</p> <p>(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and</p> <p>(5) A measurement of body weight at the time of application; and</p> <p>(6) An identified genetic mutation, if applicable; and</p> <p>(7) A family history of aHUS, if applicable; and</p>	

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			<p>(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and</p> <p>(9) A history of kidney transplant if applicable (especially if required due to aHUS); and</p> <p>(10) An inclusion of the individual consequences of recurrent disease, if applicable; and</p> <p>(11) 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; and</p> <p>(12) 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; and</p> <p>(13) 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>	
Efavirenz	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
Eltrombopag	C11199		<p>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. Patient must be aged 18 years or older. For the purpose of this restriction, a continuing response to treatment with drug is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR</p>	Compliance with Authority Required procedures

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			(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. The platelet count must be no more than 4 weeks old at the time of application.	
	C11202		<p>Severe thrombocytopenia Initial treatment 1 - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have had a splenectomy; AND Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy; AND Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be aged 18 years or older. The following criteria indicate failure to achieve an adequate response 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. Where intolerance to treatment with corticosteroid and immunoglobulin therapy 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. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, (3) details of a platelet count supporting the diagnosis of ITP. The platelet count must be no more than 4 weeks old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.</p>	Compliance with Written Authority Required procedures
	C11244		<p>Severe thrombocytopenia Balance of supply or change of therapy within 24 weeks initial treatment 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 1 restriction to complete 24 weeks treatment; OR</p>	Compliance with Authority Required procedures

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			<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR</p> <p>Patient must be swapping therapy from romiplostim to this drug for this condition within the initial 24 weeks of treatment; OR</p> <p>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 to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent 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 available under the above restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.</p>	
	C11262		<p>Severe thrombocytopenia</p> <p>Initial treatment 2 - New patient</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must not have had a splenectomy; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND</p> <p>Patient must be unsuitable for splenectomy due to medical reasons; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>Patient must be aged 18 years or older.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;</p> <p>(a) a platelet count of less than or equal to 20,000 million per L; OR</p> <p>(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>Where intolerance to treatment with corticosteroid and immunoglobulin therapy 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 authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form,</p> <p>(2) a completed Idiopathic Thrombocytopenic Purpura Initial 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
			Information Form, (3) details of a platelet count supporting the diagnosis of ITP, and (4) details of the reason of medical contraindication for surgery and date of assessment. The platelet count must be no more than 4 weeks old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.	
	C11263		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; 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; AND Patient must not have previously received PBS-subsidised continuing treatment with romiplostim for this condition; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be aged 18 years or older. For the purposes of this restriction, a sustained platelet response is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and (3) the most recent platelet count. 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.	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.	
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 alafenamide	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 naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Enfuvirtide	C5014		HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, 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.	Compliance with Authority Required procedures - Streamlined Authority Code 5014
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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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 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 5044
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

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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	C10241		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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.	Compliance with Authority Required procedures
	C11322		Pulmonary arterial hypertension (PAH) Initial 1 (starting dual therapy in an untreated patient for the first time) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor. 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, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>prostanoid is one of: (c) epoprostenol, (d) iloprost.</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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11323		<p>Pulmonary arterial hypertension (PAH)</p> <p>'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised</p> <p>Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND</p>	Compliance with Written Authority Required procedures

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			<p>The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR</p> <p>The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; 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 if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR</p> <p>The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>Applications for authorisation must be lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
	C11325		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change)</p> <p>Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p> <p>For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.</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>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
	C11329		<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must have WHO Functional Class IV PAH; 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>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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>PAH (WHO Group 1 pulmonary hypertension) is defined as follows:</p>	Compliance with Written Authority Required procedures

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			<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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C11330		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C11345		<p>Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor. 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, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost. 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. 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

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C11356		<p>Pulmonary arterial hypertension (PAH) Initial 2 (starting dual therapy in a treated patient for the first time) The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated; 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. 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; a prostanoid is one of: (f) epoprostenol, (g) iloprost. 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 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
Etanercept	C9384		<p>Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply 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 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.</p>	Compliance with Authority Required procedures
	C9417		<p>Severe active juvenile idiopathic arthritis 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</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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.</p>	
	C10548		<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; or (ii) 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 provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity</p>	Compliance with Written Authority Required procedures

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			<p>necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of 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>(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 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 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 injections to provide sufficient for four weeks of treatment. 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 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>	
	C10578		<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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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).            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 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.            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 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.            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 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 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.            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>	
	C10579		<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</p>	Compliance with Written Authority Required procedures

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			<p>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>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 submitted with the initial treatment application.</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 injections to provide sufficient for four weeks of treatment. 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 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 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. 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>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C10599		<p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 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; or (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 measures of joint count must be no more than 4 weeks old at the time of this application. 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 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. 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 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. 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 the response assessment is not submitted within this timeframe, the patient will be deemed to</p>	Compliance with Written Authority Required procedures

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			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.	
Etravirine	C5014		HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, 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.	Compliance with Authority Required procedures - Streamlined Authority Code 5014
Everolimus	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
	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
	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



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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
	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

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	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
	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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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
Fosamprenavir	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
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

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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 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.	Compliance with Authority Required procedures
	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
Grazoprevir with elbasvir	C5969	P5969	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
	C6625	P6625	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.	Compliance with Authority Required procedures

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Ibandronic acid	C5291		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5291
	C9333		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9333
Iloprost	C10229		<p>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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C11322		<p>Pulmonary arterial hypertension (PAH) Initial 1 (starting dual therapy in an untreated patient for the first time) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor. 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, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a</p>	Compliance with Written Authority Required procedures

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			<p>prostanoid is one of: (c) epoprostenol, (d) iloprost.</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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11323		<p>Pulmonary arterial hypertension (PAH)</p> <p>'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised</p> <p>Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND</p>	Compliance with Written Authority Required procedures

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			<p>The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR</p> <p>The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; 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 if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR</p> <p>The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>Applications for authorisation must be lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p>	

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			<p>(2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. 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>	
	C11325		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor. For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost. 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. 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
	C11343		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.</p>	Compliance with Written Authority Required procedures



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			<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>Applications for authorisation must be in writing and must include:            (1) a completed authority prescription form; and            (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:            (i) RHC composite assessment; and            (ii) ECHO composite assessment; and            (iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:            (1) RHC plus ECHO composite assessments;            (2) RHC composite assessment plus 6MWT;            (3) RHC composite assessment only.</p> <p>In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:            (1) ECHO composite assessment plus 6MWT;            (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 provided with the authority application.            Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11345		<p>Pulmonary arterial hypertension (PAH)            Continuing treatment (dual therapy)            Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; AND            The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</p>	Compliance with 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>For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.</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>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>	
	C11356		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (starting dual therapy in a treated patient for the first time)</p> <p>The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated; 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.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>	Compliance with Authority Required procedures
	C11365		<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</p>	Compliance with Authority Required procedures

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			<p>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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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>	
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 medical</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4524

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			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> <p>The treatment must be as systemic monotherapy (other than methotrexate).</p> <p>Must be treated by a dermatologist.</p>	Compliance with Authority Required procedures
	C8644		<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 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>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course</p>	Compliance with Written Authority Required procedures

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			<p>authorised 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 aged 18 years or older.  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 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 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(s); and  (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.  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 provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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.  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>	
	C8645		<p>Severe active rheumatoid arthritis  Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)</p>	Compliance with Written Authority Required procedures

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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 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 , or 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; or (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 aged 18 years or older.                      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 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 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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.                      To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks</p>	

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			<p>in therapy. 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>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> <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>	
	C8646		<p>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 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. Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures
	C8715		<p>Severe active rheumatoid arthritis 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 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 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</p>	Compliance with Written Authority Required procedures

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			<p>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 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; 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 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 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.</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 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) 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 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</p>	



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			<p>state the reasons why this criterion cannot be satisfied.</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>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(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>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> <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>	
	C8743		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less 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 received prior PBS-subsidised treatment with a biological medicine for this condition;</p> <p>AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; 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.</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

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			<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) 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>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>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> <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:  (1) a completed authority prescription form(s); and  (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</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>	
	C8744		<p>Severe active rheumatoid arthritis  First continuing treatment  Must be treated by a rheumatologist; OR</p>	Compliance with Written Authority Required procedures

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			<p>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; AND            The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.            Patient must be aged 18 years or older.            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 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 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(s); and            (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.            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 provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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.            If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not</p>	

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			be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8745		Severe active rheumatoid 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 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. Patient must be aged 18 years or older.	Compliance with Authority Required procedures
	C8755		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 demonstrated an adequate response to treatment with this drug; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised 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 aged 18 years or older. 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 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. The measurement of response to the prior course of therapy must be documented in the patient's	Compliance with Authority Required procedures - Streamlined Authority Code 8755

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			<p>medical notes.</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 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>	
	C8800		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Whole body (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 have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; 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 aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 1 month 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 completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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. Demonstration of response should be provided within this timeframe.</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>	Compliance with Written Authority Required procedures

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			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.	
	C8844		<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.                      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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 8844
	C8881		<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;</p>	Compliance with Written Authority Required procedures

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			<p>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.</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> <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>	
	C8883		<p>Severe chronic plaque psoriasis</p> <p>First continuing treatment, Face, hand, foot</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>The treatment must be as systemic monotherapy (other than methotrexate); 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>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,</p>	Compliance with Written Authority Required procedures

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			<p>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> <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: (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.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.</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>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 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>	
	C8886		<p>Severe chronic plaque psoriasis Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement 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</p>	Compliance with Authority Required procedures



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			<p>body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.</p> <p>Must be treated by a dermatologist.</p>	
	C8940		<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 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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 8940

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			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</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>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 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 most recent PASI assessment must be no more than 1 month old at the time of application.</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> <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 Written Authority Required procedures
	C8962		Severe chronic plaque psoriasis	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 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 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.</p>	Authority Required procedures
	C8983		<p>Severe chronic plaque psoriasis            Initial treatment - Initial 3, Face, hand, foot (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</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>PBS-subsidised biological medicine for this condition; AND                      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                      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 aged 18 years or older.                      Must be treated by a dermatologist.                      The most recent PASI assessment must be no more than 1 month 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 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.                      It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.                      To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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. Demonstration of response should be provided within this timeframe.                      The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.                      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 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>	
	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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 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>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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:                      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 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 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.                      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.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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
	C9110		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 aged 18 years or older. 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. 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. 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: 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 (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: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Written Authority Required procedures

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			<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).                      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.                      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 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.                      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.</p>	
	C9111		<p>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.</p>	Compliance with Authority Required procedures
	C9169		<p>Severe psoriatic arthritis                      Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 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 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 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 aged 18 years or older.            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 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</p>	

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			<p>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.</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>	
	C9188		<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 9188</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C9191		<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 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 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). 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. This will enable ongoing</p>	Compliance with Written Authority Required procedures

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			<p>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.</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. 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>	
	C9400		<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, 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 18 weeks of treatment under this restriction.</p> <p>Patient must be aged 18 years or older.</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> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.</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>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 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>An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>(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 supplied in all subsequent continuing treatment applications.  All measurements provided must be no more than 1 month old at the time of 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. 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>	
	C9401		<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 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or 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; or (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); or (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 aged 18 years or older.  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:  (a) a completed authority prescription form; and  (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which</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>includes the following:</p> <p>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a completed BASDAI Assessment Form.</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. 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 reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C9402		<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 aged 18 years or older.</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> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 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 supplied in all subsequent continuing treatment applications.</p> <p>All measurements provided must be no more than 1 month old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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>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.</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. 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>	
	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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9472

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Clause 1

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. 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.	
	C9481		<p>Ankylosing spondylitis                      Subsequent continuing treatment                      Must be treated by a rheumatologist; OR                      Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.                      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 under this restriction.                      Patient must be aged 18 years or older.                      An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 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 used to determine response for all subsequent continuing treatments.                      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. 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 9481
	C9487		<p>Ankylosing spondylitis                      Continuing treatment - balance of supply                      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.                      Must be treated by a rheumatologist; OR</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 clinical immunologist with expertise in the management of ankylosing spondylitis.	
	C9558		<p>Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; 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; or (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); or (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 aged 18 years or older. 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 trialled, 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: (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. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. 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: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which</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>includes the following:</p> <p>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a completed BASDAI Assessment Form; and</p> <p>(iii) a completed Exercise Program Self Certification Form included in the supporting information form.</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. 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 reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	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>	Compliance with Authority Required procedures - Streamlined Authority Code 9584

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 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:</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 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 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.</p>	
	C9587		<p>Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. 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 under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:</p> <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</p>	Compliance with Written Authority Required procedures

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			<p>(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 supplied in all subsequent continuing treatment applications. All measurements provided must be no more than 1 month 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. 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. 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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9602
	C9621		Ankylosing spondylitis	Compliance with Authority

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 ankylosing spondylitis. 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 under this restriction. Patient must be aged 18 years or older. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 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 used to determine response for all subsequent continuing treatments. 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. 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>	Required procedures - Streamlined Authority Code 9621
	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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9632

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			<p>treatment is defined by the Oxford criteria where:</p> <p>(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</p> <p>(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.</p> <p>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.</p> <p>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.</p> <p>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>	
	C9668		<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>The PCDAI assessment must be no more than 1 month old at the time of prescribing.</p> <p>The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.</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 Authority Required procedures - Streamlined Authority Code 9668
	C9669		<p>Moderate to severe Crohn disease</p> <p>Balance of supply for paediatric 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)]; OR</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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            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>	
	C9675		<p>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)            Must be treated by a gastroenterologist (code 87); OR            Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR            OR            Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR            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</p>	Compliance with Written Authority Required procedures

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			<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 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.</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 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 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>	
	C9676		<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 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</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>treatment for this condition; 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 calculation sheet including the date of the assessment of the patient's condition, if relevant; 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 clinical assessment.            All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.            The application for first continuing treatment with this drug must include an 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 undertaken and submitted 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. 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.            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.            If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient</p>	

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			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.	
	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 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 the necessity for permanent withdrawal of treatment. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the 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 eight weekly. Up to a maximum of 2 repeats will be authorised.</p>	Compliance with Written Authority Required procedures
	C9719		<p>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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR OR Must be treated by a paediatrician; 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 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.            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.            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.            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.            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.            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            OR            Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR            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</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 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 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.                      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>	
	C9731		<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                      OR                      Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].                      Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment 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</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9731</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</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. 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>	
	C9732		<p>Complex refractory Fistulising 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)].</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 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>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</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. 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
	C9733		<p>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>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 under the First continuing treatment restriction; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9733

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			<p>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</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; 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>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</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. 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>	
	C9751		<p>Moderate to 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>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>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 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 more than once in 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> <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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>which includes the following:</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and</p> <p>(ii) details of prior biological medicine treatment including 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 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.</p> <p>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. 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>	
	C9752		<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> <p>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>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 confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic</p>	Compliance with Written Authority Required procedures

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			<p>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 necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.                      Details of the accepted toxicities including severity can be found on the Department of Human Services website.                      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.                      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.                      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>	



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	
	C9754		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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR 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 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 The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.	Compliance with Authority Required procedures
	C9756		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 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 3 doses to be administered at weeks 0, 2 and 6 under this	Compliance with Written Authority Required procedures

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			<p>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 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 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 of 3 doses at 5 mg per kg body weight per 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 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.                      The 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.                      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 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>	

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. 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.	
	C9759		<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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment 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.</p>	Compliance with Written Authority Required procedures

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			<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. 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 the 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>	
	C9775		<p>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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR 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>	Compliance with Authority Required procedures - Streamlined Authority Code 9775
	C9776		<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)];</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];</p> <p>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 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 (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 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; OR</p> <p>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).</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>(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 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</p>	

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			<p>weeks following cessation of the most recent prior conventional treatment.                      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.                      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.                      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.                      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 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. Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p>	
	C9778		<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                      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 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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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            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            (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            (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> <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;            (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> <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            (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> <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>	

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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 provided at the time of application. 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 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. 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 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 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>	
	C9779		<p>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 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</p>	Compliance with Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	
	C9781		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 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 3 doses to be administered at weeks 0, 2 and 6 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 current Crohn Disease Activity Index (CDAI) calculation sheet including the date of	Compliance with Written Authority Required procedures

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			<p>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.                      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. 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.                      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.                      The 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.                      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>	
	C9783		<p>Complex refractory Fistulising 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                      OR                      Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].                      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.                      An adequate response 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>(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 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.</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> <p>A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.</p> <p>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>	
	C9785		<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>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>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; 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> <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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9785

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			<p>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.                      The measurement of response to the prior course of therapy must be documented in the patient's medical notes.                      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.                      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>	
	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                      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
	C9788		<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                      OR                      Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR                      OR                      Must be treated by a paediatrician; OR                      Must be treated by a specialist paediatric gastroenterologist.</p>	Compliance with Authority Required procedures

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 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> <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.</p> <p>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>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 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 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>	
	C9799		<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>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>OR</p> <p>Must be treated by a paediatrician; OR</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 specialist paediatric gastroenterologist.                      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 diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND                      Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30;                      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.                      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. 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.                      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.                      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.</p>	
	C9800		<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</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)]; 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 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. 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. 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, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. 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. 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</p>	

**Schedule 3** Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 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. Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p>	
	C9803		<p>Complex refractory Fistulising Crohn disease</p> <p>Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)</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 PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.</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; and</p> <p>(ii) details of prior biological medicine treatment including details of date and duration of treatment.</p> <p>The most recent fistula assessment must be no more than 1 month old at the time of application.</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</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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.</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. 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. 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 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>	
	C9806		<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>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>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; 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> <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.</p> <p>Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9806

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. 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>	
	C9877		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (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, 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 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>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. 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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. 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. 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 Information Form which includes the following: (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. 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.</p>	
	C9900		<p>Complex refractory Fistulising Crohn disease Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. 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 Patient must have an externally draining enterocutaneous or rectovaginal fistula. 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. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3</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>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 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>	
	C9975		<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 demonstrated an adequate response to treatment with this drug; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised 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 aged 18 years or older. 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 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. 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 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 9975

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	
	C9994		<p>Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological 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 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 drug for this condition during the current treatment cycle; 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 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. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. 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. Demonstration of response should be provided within this timeframe. 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. 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 Information</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>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>	
	C11094		<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>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</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 5 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; 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 aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast 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.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.</p> <p>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:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(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> <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. 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 and face, hand, foot area diagrams 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. 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. 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>	
	C11095		<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>	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>Patient must not receive more than 22 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.                      An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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.                      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. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.                      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. 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 Information Form which includes the following:                      (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.                      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.</p>	
	C11111		<p>Severe chronic plaque psoriasis                      Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological</p>	<p>Compliance with Written Authority Required procedures</p>



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			<p>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 aged 18 years or older.            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 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.            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 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 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>	
	C11112		<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 5 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;</p>	Compliance with Written Authority Required procedures

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			<p>(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; 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 aged 18 years or older.                      Must be treated by a dermatologist.                      Where treatment with methotrexate, ciclosporin, apremilast 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 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, 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 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, as assessed, preferably whilst still on treatment, but no longer than 1 month 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 1 month following cessation of the most recent prior treatment;                      (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.                      (c) The most recent PASI assessment must be no more than 1 month 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 Information Form which includes the following:                      (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].                      It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.                      To demonstrate a response to treatment the application must be accompanied with the assessment of</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia 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. Demonstration of response should be provided within this timeframe.</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. 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>	
	C11127		<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 5 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; 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 aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast 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 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, 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:</p>	Compliance with Written Authority Required procedures

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			<p>(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> <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. 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. 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 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>	
	C11128		<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 aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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.            An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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.            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 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.            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 Information Form which includes the following:            (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and            (ii) details of prior biological treatment, including dosage, date and duration 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 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.</p>	
	C11129		<p>Severe chronic plaque psoriasis            Initial treatment - Initial 3, Face, hand, foot (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 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>	Compliance with Written Authority Required procedures

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			<p>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 aged 18 years or older. 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. 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:                      (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. 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. 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>	
	C11158		<p>Severe chronic plaque psoriasis</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>	Compliance with Authority Required procedures

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 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</p> <p>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</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.</p> <p>Must be treated by a dermatologist.</p>	
	C11159		<p>Severe chronic plaque psoriasis Initial 1 - Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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 5 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; 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 aged 18 years or older.</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast 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.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.</p> <p>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:</p> <p>(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 1 month following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on</p>	Compliance with Written Authority Required procedures

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			<p>treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month 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>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia 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. Demonstration of response should be provided within this timeframe.</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. 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>	
Interferon alfa-2a	C4993		<p>Chronic hepatitis B infection</p> <p>Patient must not have cirrhosis, AND</p> <p>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</p> <p>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</p> <p>Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4993
	C5036		<p>Chronic hepatitis B infection</p> <p>Patient must have cirrhosis, AND</p> <p>Patient must have detectable HBV DNA.</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5036



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			transplant unit prior to initiating therapy.	
	C5042		Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Authority Required procedures - Streamlined Authority Code 5042
	C9259		Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Authority Required procedures - Streamlined Authority Code 9259
Interferon Gamma-1b	C6222		Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6222
	C9639		Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Authority Required procedures - Streamlined Authority Code 9639
Ivacaftor	C9889		Cystic fibrosis Continuing treatment 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 Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 12 months or older. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. 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	Compliance with Written Authority Required procedures

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			<p>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 form; and</p> <p>(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and</p> <p>(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(5) height and weight measurements at the time of application; and</p> <p>(6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.</p>	
	C9890		<p>Cystic fibrosis</p> <p>Initial treatment - New patients</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 have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis; 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 12 months or older.</p> <p>Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</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> <ol style="list-style-type: none"> <li>(1) a completed authority prescription form; and</li> <li>(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and</li> <li>(3) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and</li> <li>(4) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</li> <li>(5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</li> <li>(6) sweat chloride result; and</li> <li>(7) height and weight measurements at the time of application; and</li> <li>(8) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.</li> </ol>	
Lamivudine	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</p>	Compliance with Authority Required procedures - Streamlined

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			The treatment must be in combination with other antiretroviral agents	Authority Code 4512
	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 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	Compliance with Authority Required procedures - Streamlined Authority Code 7025

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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>	
	C7042		<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 (6 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 7042
	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.</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7532

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			<p>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 lanreotide 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 pegvisomant.                      In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</p>	
	C9225		<p>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 lanreotide has been withdrawn for at least 4 weeks (6 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 pegvisomant.                      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 9225
	C9260		<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9260
	C9261		<p>Acromegaly                      The condition must be active; AND</p>	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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 9261
	C10061		<p>Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)</p> <p>The condition must be unresectable locally advanced disease or metastatic disease; AND</p> <p>The condition must be World Health Organisation (WHO) grade 1 or 2; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patient must be aged 18 years or older.</p> <p>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.</p> <p>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10061
	C10075		<p>Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must be unresectable locally advanced disease or metastatic disease; AND</p> <p>The condition must be World Health Organisation (WHO) grade 1 or 2; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patient must be aged 18 years or older.</p> <p>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.</p> <p>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10075
	C10077		<p>Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)</p> <p>The condition must be unresectable locally advanced disease or metastatic disease; AND</p> <p>The condition must be World Health Organisation (WHO) grade 1 or 2; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patient must be aged 18 years or older.</p> <p>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.</p> <p>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10077
Lanthanum	C5530		Hyperphosphataemia	Compliance with Authority

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	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
Ledipasvir with sofosbuvir	C5944	P5944	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 8 weeks.	Compliance with Authority Required procedures
	C5969	P5969	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
	C5972	P5972	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 24 weeks.	Compliance with Authority Required procedures
Lenalidomide	C4282		Myelodysplastic syndrome Continuing treatment	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS); AND</p> <p>Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND</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 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.</p> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p> <p>The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.</p> <p>The following evidence of response must be provided at each application:</p> <p>(i) a haemoglobin level taken within the last 4 weeks; and</p> <p>(ii) the date of the last transfusion; and</p> <p>(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and</p> <p>(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.</p>	
	C4287		<p>Myelodysplastic syndrome</p> <p>Initial treatment</p> <p>The treatment must be limited to a maximum duration of 16 weeks; AND</p> <p>Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS); AND</p> <p>Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND</p> <p>Patient must be red blood cell transfusion dependent.</p> <p>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.</p> <p>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"> <li>1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR</li> <li>2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR</li> <li>3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR</li> <li>4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR</li> </ol>	Compliance with Written Authority Required procedures

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			<p>5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR</p> <p>6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR</p> <p>7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.</p> <p>Classification of a patient as red blood cell transfusion dependent requires that:</p> <p>(i) the patient has been transfused within the last 8 weeks; and</p> <p>(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> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</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 Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and</p> <p>(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and</p> <p>(d) a copy of the full blood examination report; and</p> <p>(e) a copy of the pathology report detailing 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>(f) 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 cell units transfused in the 4 and 6 months preceding the date of this application; and</p> <p>(g) a signed patient acknowledgement form.</p>	
	C10334		<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 in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the date the autologous stem cell transplant was performed, and nomination of which disease activity parameters will be used to assess progression.</p> <p>To enable confirmation of eligibility for treatment, the results of current diagnostic reports of at least one</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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; 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 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 provided.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
	C10335		<p>Multiple myeloma</p> <p>Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have demonstrated progressive disease; AND</p> <p>The treatment must be as monotherapy.</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>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C10349		<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 be in combination with dexamethasone; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures
	C10350		<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 be in combination with 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; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. 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. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) a signed patient acknowledgment.</p> <p>To enable confirmation of eligibility for treatment, current diagnostic reports 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; 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 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 provided.</p> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p>	
	C10373		<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>Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND</p> <p>The treatment must be in combination with dexamethasone.</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 Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) a signed patient acknowledgement.</p> <p>To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:</p>	Compliance with Written Authority Required procedures

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			<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; 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.                      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 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 provided.                      Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
	C10427		<p>Multiple myeloma                      Continuing treatment until progression in patients initiated on dual combination therapy (lenalidomide and dexamethasone), or, in patients initiated on triple therapy (lenalidomide, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond                      Patient must have previously been authorised with a PBS prescription with this drug for the condition;                      AND                      Patient must not have demonstrated progressive disease; AND                      Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues;                      AND                      The treatment must be in combination with dexamethasone.                      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).</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C10428		<p>Multiple myeloma</p> <p>Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle</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 not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND</p> <p>The treatment must be in combination with bortezomib and dexamethasone; AND</p> <p>Patient must not have been treated with lenalidomide or bortezomib for this condition; AND</p> <p>The treatment must not exceed a total of 4 cycles under this restriction.</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 Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response.</p> <p>To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) 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; 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 and kept on the patient's records. 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 declared to be held on the patient's medical records.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Written Authority Required procedures
	C10429		<p>Multiple myeloma</p> <p>Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment</p>	Compliance with Authority Required procedures

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			<p>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                      Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues;                      AND                      The treatment must be in combination with bortezomib and dexamethasone; AND                      The treatment must not exceed a total of 2 cycles under this restriction.                      Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
	C10452		<p>Multiple myeloma                      Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)                      Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND                      Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues;                      AND                      The treatment must be in combination with bortezomib and dexamethasone; AND                      The treatment must not exceed a total of 4 cycles under this restriction.                      Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures
	C10453		<p>Multiple myeloma                      Initial treatment with triple therapy (lenalidomide, 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                      Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues;                      AND                      The treatment must be in combination with bortezomib and 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 in writing and must include:                      (1) a completed authority prescription form; and                      (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response.                      To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided:                      (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</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			(d) bone marrow aspirate or trephine; 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. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. 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 declared to be held on the patient's medical records. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
Lenograstim	C6502		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.	Compliance with Authority Required procedures - Streamlined Authority Code 6502
	C6507		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.	Compliance with Authority Required procedures - Streamlined Authority Code 6507
	C6516		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.	Compliance with Authority Required procedures - Streamlined Authority Code 6516
	C6522		Chemotherapy-induced neutropenia Patient must be receiving standard dose adjuvant chemotherapy for breast cancer; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre); AND The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule; AND Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.	Compliance with Authority Required procedures - Streamlined Authority Code 6522
	C6523		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.	Compliance with Authority Required procedures - Streamlined

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				Authority Code 6523
	C6532		Chemotherapy-induced neutropenia Patient must be receiving first-line chemotherapy for Hodgkin disease; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre); AND The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule; AND Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.	Compliance with Authority Required procedures - Streamlined Authority Code 6532
	C6535		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.	Compliance with Authority Required procedures - Streamlined Authority Code 6535
	C6634		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.	Compliance with Authority Required procedures - Streamlined Authority Code 6634
	C6644		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.	Compliance with Authority Required procedures - Streamlined Authority Code 6644
	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
	C6657		Assisting peripheral blood progenitor cell or bone marrow 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 6657
	C6673		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).	procedures - Streamlined Authority Code 6673
	C6682		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.	Compliance with Authority Required procedures - Streamlined Authority Code 6682
	C9226		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.	Compliance with Authority Required procedures - Streamlined Authority Code 9226
	C9227		Assisting peripheral blood progenitor cell or bone marrow 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 9227
	C9229		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9229
	C9230		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.	Compliance with Authority Required procedures - Streamlined Authority Code 9230
	C9231		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 9231
	C9263		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.	Compliance with Authority Required procedures - Streamlined Authority Code 9263
	C9264		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).	Compliance with Authority Required procedures - Streamlined Authority Code 9264
	C9265		Chemotherapy-induced neutropenia	Compliance with Authority

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			Patient must be receiving standard dose adjuvant chemotherapy for breast cancer; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre); AND The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule; AND Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.	Required procedures - Streamlined Authority Code 9265
	C9266		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.	Compliance with Authority Required procedures - Streamlined Authority Code 9266
	C9314		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 9314
	C9324		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.	Compliance with Authority Required procedures - Streamlined Authority Code 9324
	C9325		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.	Compliance with Authority Required procedures - Streamlined Authority Code 9325
	C9326		Chemotherapy-induced neutropenia Patient must be receiving first-line chemotherapy for Hodgkin disease; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre); AND The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule; AND Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.	Compliance with Authority Required procedures - Streamlined Authority Code 9326
	C9327		Chemotherapy-induced neutropenia Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.	Compliance with Authority Required procedures - Streamlined Authority Code 9327

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
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 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
	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

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	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	C9857		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 be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (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; 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. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor 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.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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 form; and</p> <p>(2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and</p> <p>(3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and</p> <p>(4) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</p> <p>(5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(6) height and weight measurements at the time of application; and</p> <p>(7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the-home) in the previous 12 months.</p>	
	C9891		<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> <p>Patient must be aged between 6 and 11 years inclusive.</p> <p>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</p> <p>Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.</p> <p>For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.</p> <p>Lumacaftor 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>	Compliance with Written Authority Required procedures

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			(1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and (3) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.	
	C9920		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 be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (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; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition. Patient must be aged between 6 and 11 years inclusive. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor 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 form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>(3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and</p> <p>(4) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</p> <p>(5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(6) height and weight measurements at the time of application; and</p> <p>(7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-home) in the previous 12 months.</p>	
	C9943		<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 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>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</p> <p>Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.</p> <p>For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.</p> <p>Lumacaftor 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 form; and</p> <p>(2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and</p> <p>(3) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute</p>	Compliance with Written Authority Required procedures

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			<p>infective exacerbation at the time FEV1 is measured; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(5) height and weight measurements at the time of application; and</p> <p>(6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.</p>	
	C10005		<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> <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 2 years of age or older.</p> <p>The patient must be registered in the Australian Cystic Fibrosis Database Registry.</p> <p>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</p> <p>For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.</p> <p>Lumacaftor 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 form; and</p> <p>(2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and</p> <p>(3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and</p> <p>(4) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</p> <p>(5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(6) height and weight measurements at the time of application; and</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			(7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months. For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV1 and hospitalisation dates prior to initiating treatment (where available) should be provided.	
	C10007		<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> <p>Patient must be 2 years of age or older.</p> <p>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</p> <p>Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.</p> <p>For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.</p> <p>Lumacaftor 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 form; and</p> <p>(2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and</p> <p>(3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(5) height and weight measurements at the time of application; and</p> <p>(6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6</p>	Compliance with Written Authority Required procedures

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			months.	
Macitentan	C10228		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10236		<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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10285		<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</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 been assessed by a physician with expertise in the management of PAH; 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.  The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.  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.  Applications for authorisation must be in writing and must include:  (1) a completed authority prescription form; and  (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:  (i) RHC composite assessment; and  (ii) ECHO composite assessment; and  (iii) 6 Minute Walk Test (6MWT).  Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:  (1) RHC plus ECHO composite assessments;  (2) RHC composite assessment plus 6MWT;  (3) RHC composite assessment only.  In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:  (1) ECHO composite assessment plus 6MWT;  (2) ECHO composite assessment only.  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 provided with the authority application.  Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.  The test results provided must not be more than 2 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.</p>	

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	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 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
	C11312		<p>Pulmonary arterial hypertension (PAH)                      Initial 1 (starting dual therapy in an untreated patient for the first time)                      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.                      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)</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11313		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment (dual therapy)</p> <p>Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; AND</p>	Compliance with Authority Required procedures

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			<p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</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>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>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>	
	C11314		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (starting dual therapy in a treated patient for the first time)</p> <p>The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR</p> <p>The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated;</p> <p>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 endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>	Compliance with Authority Required procedures
	C11317		<p>Pulmonary arterial hypertension (PAH)</p>	Compliance with Written



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			<p>Grandfathered patient (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020; AND Patient must have documented WHO Functional Class III PAH or WHO Functional 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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes ambrisentan, bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. 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. 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. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority</p>	Authority Required procedures

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			<p>application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. 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>	
	C11321		<p>Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor. 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. 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
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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7362

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			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.	
	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 trialed 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 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 7367
	C9527		<p>Cystic fibrosis</p> <p>The treatment must be as monotherapy; AND</p> <p>Patient must be intolerant or inadequately responsive to dornase alfa.</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>	Compliance with Authority Required procedures - Streamlined Authority Code 9527

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			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.	
	C9593		<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 trialed 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 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 9593
Maraviroc	C5008		<p>HIV infection</p> <p>Patient must be infected with CCR5-tropic HIV-1, AND</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 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> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5008
Mepolizumab	C9885	P9885	<p>Uncontrolled severe eosinophilic asthma</p> <p>Balance of supply</p> <p>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.</p> <p>Patient must received insufficient therapy with this drug under the Initial 1 (new patients or</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR            Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 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 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            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>	
	C10221	P10221	<p>Uncontrolled severe eosinophilic asthma            Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)            Must be treated by a respiratory physician, clinical immunologist, allergist or 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            Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND            Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR            Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND            Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR            Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND            Patient must have a duration of asthma of at least 1 year; AND            Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR            Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND            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; AND            Patient must not receive more than 32 weeks of treatment under this restriction; AND            The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.            Patient must be aged 12 years or older.</p>	Compliance with Written Authority Required procedures

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			<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, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.</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 3 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>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>A respiratory physician; and</p> <p>A pharmacist, nurse or asthma educator.</p>	

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			<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 Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form,</p> <p>which includes the following:</p> <p>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and</p> <p>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and</p> <p>(iii) the eosinophil count and date; and</p> <p>(iv) Asthma Control Questionnaire (ACQ-5) score.</p>	
	C10222	P10222	<p>Uncontrolled severe eosinophilic asthma Initial treatment - Initial 2 (Change of treatment)</p> <p>Must be treated by a respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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>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 Severe Eosinophilic Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:</p> <p>(i) 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>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and</p> <p>(iii) eosinophil count and date; and</p> <p>(iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p>	Compliance with Written Authority Required procedures

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			<p>(v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</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 continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, 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 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:                      A respiratory physician; and                      A pharmacist, nurse or asthma educator.</p>	
	C10280	P10280	<p>Uncontrolled severe eosinophilic asthma                      Continuing treatment                      Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.                      Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug 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 severe asthma; AND                      Patient must not receive more than 24 weeks of treatment under this restriction.                      Patient must be aged 12 years or older.                      An adequate response to this biological medicine is defined as:                      (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,                      OR                      (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.                      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 at around 20 weeks after the first dose of PBS-subsidised dose of</p>	Compliance with Written Authority Required procedures



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			<p>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 submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, 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> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes:</p> <p>(i) details of maintenance oral corticosteroid dose; or</p> <p>(ii) a completed Asthma Control Questionnaire (ACQ-5) score.</p>	
	C10483	P10483	<p>Uncontrolled severe eosinophilic asthma</p> <p>Grandfather treatment - use in a patient initiated with non-PBS subsidised pre-filled syringe or pen device</p> <p>Patient must have received non-PBS-subsidised treatment with this biological medicine's pre-filled syringe or pen device for this PBS-indication prior to 1 June 2020; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine; AND</p> <p>Patient must be receiving treatment with this drug for this condition at the time of application; AND</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 with severe asthma by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have had, prior to commencement of this drug, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) peak</p>	Compliance with Written Authority Required procedures

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			<p>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 had, prior to commencement of this drug, a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND</p> <p>Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of a biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to commencement of a biological medicine treatment for severe asthma; AND</p> <p>Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy prior to commencement of this biological medicine despite formal assessment of and adherence to correct inhaler technique, which has been documented; 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>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with 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 12 months prior to commencing treatment with a biological medicine for severe asthma, 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 (if not already provided).</p> <p>The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be declared to have been met at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; AND</p> <p>(b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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>An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in</p>	

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			<p>the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.</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 3 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:  A respiratory physician; and  A pharmacist, nurse or asthma educator.</p> <p>An adequate response to this biological medicine is defined as:  (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,  OR  (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>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</p> <p>The authority application must be made in writing and must include:  (a) a completed authority prescription form; and  (b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form which seeks details of the following (if not already provided):  (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and  (ii) eosinophil pathology report (eosinophil counts and dates); and  (iii) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose.</p>	
	C10484	P10484	<p>Uncontrolled severe eosinophilic asthma  Grandfather treatment - use in a patient initiated with non-PBS-subsidised pre-filled syringe or pen device</p> <p>Patient must have received non-PBS-subsidised treatment with this biological medicine's pre-filled syringe or pen device for this PBS-indication prior to 1 June 2020; AND  Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine; AND  Patient must be receiving treatment with this drug for this condition at the time of application; AND  Patient must be under the care of the same physician for at least 6 months; OR</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have been diagnosed with severe asthma by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have had, prior to commencement of this drug, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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 had, prior to commencement of this drug, a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND</p> <p>Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of a biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to commencement of a biological medicine treatment for severe asthma; AND</p> <p>Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy prior to commencement of this biological medicine despite formal assessment of and adherence to correct inhaler technique, which has been documented; 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>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with 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; 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 12 months prior to commencing treatment with a biological medicine for severe asthma, 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 (if not already provided).</p> <p>The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>and must be declared to have been met at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; AND</p> <p>(b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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>An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.</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 3 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> <p>A respiratory physician; and</p> <p>A pharmacist, nurse or asthma educator.</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>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</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 Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form which seeks details of the following (if not already provided):</p> <p>(i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and</p> <p>(ii) eosinophil pathology report (eosinophil counts and dates); and</p> <p>(iii) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose.</p>	

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Methoxsalen	C10971	P10971	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Initial treatment 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 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 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 14247 of the Medicare Benefits Schedule; AND Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. Patient must be aged 18 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 10971
	C10985	P10985	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Initial treatment 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 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 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 14247 of the Medicare Benefits Schedule; AND Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. Patient must be aged 18 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 10985
	C10988	P10988	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	Compliance with Authority Required procedures - Streamlined Authority Code 10988

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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 14249 of the Medicare Benefits Schedule.</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>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>	
	C10989	P10989	<p>Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma</p> <p>Continuing treatment</p> <p>Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND</p> <p>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</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication;</p> <p>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 14249 of the Medicare Benefits Schedule.</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>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>	Compliance with Authority Required procedures - Streamlined Authority Code 10989
Methoxy polyethylene glycol-epoetin beta	C6294		<p>Anaemia associated with intrinsic renal disease</p> <p>Patient must require transfusion; AND</p> <p>Patient must have a haemoglobin level of less than 100 g per L; AND</p> <p>Patient must have intrinsic renal disease, as assessed by a nephrologist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		<p>Anaemia associated with intrinsic renal disease</p> <p>Patient must require transfusion; AND</p> <p>Patient must have a haemoglobin level of less than 100 g per L; AND</p> <p>Patient must have intrinsic renal disease, as assessed by a nephrologist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Midostaurin	C8138	P8138	<p>Acute Myeloid Leukaemia</p> <p>Maintenance therapy - Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under</p>	Compliance with Authority Required procedures

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			<p>the initial maintenance or the initial maintenance grandfathering 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.                      A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p>	
	C8177	P8177	<p>Acute Myeloid Leukaemia                      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; AND                      Patient must not be undergoing or have undergone a stem cell transplant; AND                      The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.                      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 in writing and must include:                      (1) a completed authority prescription form;                      (2) a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			(3) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and (4) confirmation that the patient does not have progressive disease; and (5) a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and (6) a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.	
	C8193	P8193	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 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; 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 FLT3 ITD or TKD mutation test result and date of testing must be provided at the time of application. 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.	Compliance with Authority Required procedures
	C8218	P8218	Acute Myeloid Leukaemia Maintenance therapy - Grandfathered treatment Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin; AND	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 not be undergoing or have undergone a stem cell transplant; AND                      The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.                      A maximum of 2 cycles will be authorised under this restriction in a lifetime.                      A patient may qualify for PBS-subsidised treatment under this restriction once only.                      For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the maintenance therapy continuing treatment criteria.                      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 in writing and must include:                      (1) a completed authority prescription form;                      (2) a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and                      (3) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and                      (4) confirmation that the patient does not have progressive disease; and                      (5) a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and                      (6) a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.</p>	
Mycophenolic Acid	C4084		<p>Prophylaxis of renal allograft rejection                      Management                      The treatment must be under the supervision and direction of a transplant unit.</p>	Compliance with Authority Required Procedures – Streamlined Authority Code 4084
	C4095		<p>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.</p>	Compliance with Authority Required Procedures – Streamlined Authority Code 4095
	C5554		<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5554

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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 The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined 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	C9744		Clinically definite relapsing-remitting multiple sclerosis	Compliance with Authority

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			<p>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.                      Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.</p>	<p>Required procedures - Streamlined Authority Code 9744</p>
	C9818		<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.                      Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9818</p>
Nevirapine	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>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 4454</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	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
Nusinersen	C11049		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 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. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard of 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. Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.	Compliance with Authority Required procedures
	C11050		Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA) Initial treatment of symptomatic Type I, II or IIIa SMA - 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 be given concomitantly with standard of care for this condition; AND	Compliance with Written Authority Required procedures

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			<p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction. Patient must be 18 years of age or under.</p> <p>Defined signs and symptoms of type I SMA are:</p> <ul style="list-style-type: none"> <li>i) Onset before 6 months of age; and</li> <li>ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or</li> <li>iii) Proximal weakness; or</li> <li>iv) Hypotonia; or</li> <li>v) Absence of deep tendon reflexes; or</li> <li>vi) Failure to gain weight appropriate for age; or</li> <li>vii) Any active chronic neurogenic changes; or</li> <li>viii) A compound muscle action potential below normative values for an age-matched child.</li> </ul> <p>Defined signs and symptoms of type II SMA are:</p> <ul style="list-style-type: none"> <li>i) Onset between 6 and 18 months; and</li> <li>ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or</li> <li>iii) Proximal weakness; or</li> <li>iv) Weakness in trunk righting/derotation; or</li> <li>v) Hypotonia; or</li> <li>vi) Absence of deep tendon reflexes; or</li> <li>vii) Failure to gain weight appropriate for age; or</li> <li>viii) Any active chronic neurogenic changes; or</li> <li>ix) A compound muscle action potential below normative values for an age-matched child.</li> </ul> <p>Defined signs and symptoms of type IIIa SMA are:</p> <ul style="list-style-type: none"> <li>i) Onset between 18 months and 3 years of age; and</li> <li>ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or</li> <li>iii) Proximal weakness; or</li> <li>iv) Hypotonia; or</li> <li>v) Absence of deep tendon reflexes; or</li> <li>vi) Failure to gain weight appropriate for age; or</li> <li>vii) Any active chronic neurogenic changes; or</li> <li>viii) A compound muscle action potential below normative values for an age-matched child.</li> </ul> <p>Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.</p> <p>Application for authorisation of initial treatment must be in writing and must include:</p> <ul style="list-style-type: none"> <li>(a) a completed authority prescription form; and</li> <li>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following: <ul style="list-style-type: none"> <li>i) specification of SMA type (I, II or IIIa); and</li> <li>ii) sign(s) and symptom(s) that the patient has experienced; and</li> <li>iii) patient's age at the onset of sign(s) and symptom(s).</li> </ul> </li> </ul>	
	C11058		Pre-symptomatic spinal muscular atrophy (SMA)	Compliance with Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - 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 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 standard of care for this condition; AND The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction. 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) Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.</p>	Authority Required procedures
Ocrelizumab	C7386		<p>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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7386
	C7699		<p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 7699

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			<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>	
	C9523		<p>Multiple sclerosis 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; 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>	Compliance with Authority Required procedures - Streamlined Authority Code 9523
	C9635		<p>Multiple sclerosis 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 9635
Octreotide	C5901		<p>Functional carcinoid tumour</p> <p>Patient must have achieved symptom control on octreotide immediate release injections, 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.</p> <p>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 5901
	C5906		<p>Vasoactive intestinal peptide secreting tumour (VIPoma)</p> <p>Patient must have achieved symptom control on octreotide immediate release injections, 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 30 mg every 28 days and having allowed</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5906



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	
	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 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 6390
	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	Compliance with Authority Required procedures - Streamlined Authority Code 8165

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			<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 octreotide has been withdrawn for at least 4 weeks; AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission</p>	
	C8197		<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 controlled with octreotide immediate release injections; AND</p> <p>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</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 lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide 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 8197
	C8198		<p>Vasoactive intestinal peptide secreting tumour (VIPoma)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved symptom control on octreotide immediate release injections; 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.</p> <p>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 8198
	C8208		<p>Functional carcinoid tumour</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved symptom control on octreotide immediate release injections; 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 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.</p> <p>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 8208
	C9232		<p>Vasoactive intestinal peptide secreting tumour (VIPoma)</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</p>	Compliance with Authority Required procedures - Streamlined

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			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.	Authority Code 9232
	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 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	Compliance with Authority Required procedures - Streamlined Authority Code 9288

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			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 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10077

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			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.	
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 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:	Compliance with Written Authority Required procedures

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			(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.	
	C9855		Uncontrolled severe allergic asthma Balance of supply in a patient aged 12 years or older Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must 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 Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 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 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 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.	Compliance with Authority Required procedures
	C10219		Uncontrolled severe allergic asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a respiratory physician, clinical immunologist, allergist or 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 Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND 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 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 Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma (omalizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following: (i) 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 (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and (iii) the IgE results; and (iv) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy). 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. 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. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine. 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. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator.</p>	
	C10223		<p>Uncontrolled severe allergic asthma Balance of supply in a patient aged 6 to 12 years Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or 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</p>	Compliance with Authority Required procedures

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			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.	
	C10226		<p>Uncontrolled severe allergic asthma Continuing treatment Patient must have a documented history of severe allergic asthma; AND Patient must have demonstrated or sustained 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 paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR (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 (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. 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 must be made at around 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab. 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. 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 the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures



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			(b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of: (i) maintenance oral corticosteroid dose; and (ii) Asthma Control Questionnaire (ACQ-5) score; or (iii) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.	
	C10265		<p>Uncontrolled severe allergic asthma</p> <p>Initial treatment</p> <p>Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or 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 skin prick testing or an in vitro measure of specific IgE; AND</p> <p>Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; 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; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction.</p> <p>Patient must be aged 6 to less than 12 years.</p> <p>Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or 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; 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 initial IgE assessment must be no more than 12 months old at the time of 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</p>	Compliance with Written Authority Required procedures

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			<p>ACQ-IA be used), AND (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. 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 there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab. 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. 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. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the IgE result; and (iv) Asthma Control Questionnaire (ACQ-5) score; or (v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p>	
	C10279		<p>Uncontrolled severe allergic asthma Continuing treatment Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</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 respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.</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 must be made at around 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 and for the application for continuing therapy to be processed. 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 submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, 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 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 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 Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of:</p> <p>(i) maintenance oral corticosteroid dose; or</p> <p>(ii) Asthma Control Questionnaire (ACQ-5) score including the date of assessment of the patient's symptoms; or</p> <p>(iii) for patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the exacerbation rate has reduced.</p>	

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	C10299		<p>Uncontrolled severe allergic 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 respiratory physician, clinical immunologist, allergist or 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 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 by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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; 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 skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old; AND</p> <p>Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; 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; 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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>must be provided in the Authority application.</p> <p>The initial IgE assessment must be no more than 12 months old at the time of 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 submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, 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 3 biological medicines for severe asthma within the same treatment cycle.</p> <p>A treatment break in PBS-subsidised omalizumab therapy of at least 6 months must be observed in a patient with uncontrolled severe allergic asthma, in whom omalizumab is the only appropriate treatment option, and who has either failed to achieve or sustain a response to the most recent PBS-subsidised omalizumab therapy.</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> <p>A respiratory physician; and</p> <p>A pharmacist, nurse or asthma educator.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p>	

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			(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following: (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the IgE result; and (iv) Asthma Control Questionnaire (ACQ-5) score.	
Pamidronic Acid	C4433		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy	Compliance with Authority Required procedures – Streamlined Authority Code 4433
	C5218		Multiple Myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5218
	C5291		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5291
	C9234		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with 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		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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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.</p> <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. 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>Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:</p> <p>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> <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 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 b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and 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 d) a recent result of GH or IGF-1 levels must be provided.</p>	
	C9089		<p>Acromegaly Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. 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 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
Pegfilgrastim	C7822		Chemotherapy-induced neutropenia	Compliance with Authority

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			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.	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
	C9235		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 9235
	C9303		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 9303
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.	Compliance with Authority Required



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Patient must be aged 18 years or older; AND</p> <p>Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.</p> <p>Patient must have compensated liver disease; AND</p> <p>Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND</p> <p>Patient must have a contraindication to ribavirin; AND</p> <p>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</p> <p>The treatment must be limited to a maximum duration of 48 weeks.</p> <p>Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.</p>	procedures - Streamlined Authority Code 9603
Pegvisomant	C7087		<p>Acromegaly</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue; 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>	Compliance with Authority Required procedures
	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.</p> <p>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> <p>1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR</p>	Compliance with Written Authority Required procedures

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			<p>2) IGF-1 level is greater than the age- and sex-adjusted ULN.                      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.                      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.                      Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).                      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.                      The authority application must be made in writing and must include:                      a) two completed authority prescription forms ; and                      b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and                      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                      d) a recent result of the IGF-1 level and the date of assessment ; and                      e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide                      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                      The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND                      Patient must have lymphoma; OR                      Patient must have multiple myeloma; AND                      Patient must require autologous stem cell transplantation; AND                      Patient must have failed previous stem cell collection; OR                      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                      Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.                      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

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	C9329		Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; OR Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND Patient must have failed previous stem cell collection; OR 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 Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9329
Pomalidomide	C7791		Multiple myeloma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have progressive disease; AND The treatment must be in combination with dexamethasone; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. 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). Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	Compliance with Authority Required procedures
	C7952		Multiple myeloma Initial treatment The treatment must be in combination with dexamethasone; AND Patient must have undergone or be ineligible for a primary stem cell transplant; AND Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not	Compliance with Written Authority Required procedures

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			<p>tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.</p> <p>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>If treatment with either bortezomib or lenalidomide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to either bortezomib or lenalidomide treatment develops 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>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>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 Multiple Myeloma pomalidomide Authority Application Supporting Information form; and</p> <p>(3) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide; and</p> <p>(4) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to bortezomib.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
Raltegravir	C4274		HIV infection Continuing	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have previously received PBS-subsidised therapy for HIV infection. Patient must be aged 2 years or older.	procedures - Streamlined Authority Code 4274
	C4275		HIV infection Initial The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease. Patient must be aged 2 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 4275
	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
Ribavirin	C5957	P5957	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
	C5958	P5958	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 24 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

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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
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	C6645		Chronic thromboembolic pulmonary hypertension (CTEPH) Continuing treatment 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 aged 18 years or older. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). 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: (1) RHC plus ECHO composite assessments plus 6MWT;	Compliance with Written Authority Required procedures

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			<p>(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> <p>The results of the same tests as conducted at baseline should be provided with each written 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 provided with the application.</p> <p>The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.</p> <p>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.</p> <p>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.</p> <p>The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment. A maximum of 5 repeats will be authorised.</p> <p>Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.</p> <p>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.</p>	
	C6664		<p>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 aged 18 years or older.  CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:  Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than</p>	Compliance with Written Authority Required procedures

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			<p>300 dyn*sec*cm-5 measured at least 90 days after start of full anticoagulation; and                      A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.</p> <p>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 demonstrating the dysfunction must be provided at the time of application.</p> <p>Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.</p> <p>In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (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 provided with the authority application.</p> <p>The test results provided must not be more than 2 months old at the time of application.</p> <p>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. 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>	



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	C7629		<p>Chronic thromboembolic pulmonary hypertension (CTEPH)</p> <p>Balance of supply</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; AND</p> <p>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</p> <p>The treatment must be the sole PBS-subsidised agent for this condition.</p> <p>Must be treated in a centre with expertise in the management of CTEPH.</p> <p>Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures
	C10231		<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>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10243		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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</p>	Compliance with Authority Required procedures

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			<p>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>	
	C10245		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must have been assessed by a physician with expertise in the management of PAH; AND</p> <p>Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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>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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted</p>	Compliance with Written Authority Required procedures

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			<p>for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
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
Rituximab	C7021		<p>Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)</p> <p>Re-induction of remission</p> <p>The treatment must be for the re-induction of remission; AND</p> <p>Patient must have previously received and responded to this drug for this condition; AND</p> <p>The treatment must in combination with glucocorticoids; AND</p> <p>Patient must be at risk of end-organ damage or mortality; AND</p> <p>Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.</p> <p>Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.</p> <p>This drug is not PBS-subsidised for maintenance of remission</p> <p>The authority application must be made in writing</p>	Compliance with Written Authority Required procedures
	C7022		<p>Severe active microscopic polyangiitis</p> <p>Re-induction of remission</p> <p>The treatment must be for the re-induction of remission; AND</p> <p>Patient must have previously received and responded to this drug for this condition; AND</p>	Compliance with Written Authority Required procedures

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			<p>The treatment must in combination with glucocorticoids; AND                      Patient must be at risk of end-organ damage or mortality; AND                      Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.                      Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.                      This drug is not PBS-subsidised for maintenance therapy.                      The authority application must be made in writing</p>	
	C9336		<p>Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)                      Re-induction of remission                      The treatment must be for the re-induction of remission; AND                      Patient must have previously received and responded to this drug for this condition; AND                      The treatment must in combination with glucocorticoids; AND                      Patient must be at risk of end-organ damage or mortality; AND                      Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.                      Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.                      This drug is not PBS-subsidised for maintenance of remission</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9336</p>
	C9340		<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 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.                      Patient must be aged 18 years or older.                      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 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</p>	<p>Compliance with Written Authority Required procedures</p>

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			<p>marker will 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(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.</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>Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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>	
	C9344		<p>Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)</p> <p>Induction of remission</p> <p>The treatment must be for the induction of remission; AND</p> <p>Patient must not have previously received this drug for this condition; AND</p> <p>The treatment must in combination with glucocorticoids; AND</p> <p>Patient must be at risk of end-organ damage or mortality; AND</p> <p>Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.</p> <p>Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.</p> <p>This drug is not PBS-subsidised for maintenance of remission</p> <p>The authority application must be made in writing</p>	Compliance with Written Authority Required procedures
	C9446		<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 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9446

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			<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) 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 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.                      The measurement of response to the prior course of therapy must be documented in the patient's medical notes.                      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>	
	C9448		<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;                      AND                      Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist 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 , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND                      Patient must not receive more than 2 infusions of this drug 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 aged 18 years or older.                      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;</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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, 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>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.</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> <p>A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.</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 Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</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 a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.</p>	
	C9449		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more</p>	Compliance with Written Authority Required procedures

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			<p>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 have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist 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 , or 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; or (b) at least 4 active major joints; AND                      Patient must not receive more than 2 infusions of this drug 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 aged 18 years or older.                      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.                      The authority application must be made in writing and must include:                      (1) a completed authority prescription form(s); and                      (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.                      To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the</p>	



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			<p>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>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> <p>A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.</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 a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.</p>	
	C9450		<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; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 2 infusions of this drug 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 aged 18 years or older. 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 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. The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

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			<p>(1) a completed authority prescription form(s); and                      (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.                      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 provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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.                      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>	
	C9511		<p>Severe active microscopic polyangiitis                      Induction of remission                      The treatment must be for the induction of remission; AND                      Patient must not have previously received this drug for this condition; AND                      The treatment must in combination with glucocorticoids; AND                      Patient must be at risk of end-organ damage or mortality; AND                      Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.                      Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.                      This drug is not PBS-subsidised for maintenance therapy.                      The authority application must be made in writing</p>	Compliance with Written Authority Required procedures
	C9512		<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 have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist 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 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>	Compliance with Written 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 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 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND</p> <p>Patient must not receive more than 2 infusions of this drug 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 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 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.</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 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) 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 one month old at</p>	

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			<p>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>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:</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>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> <p>A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.</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 a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.</p>	
	C9539		<p>Severe active microscopic polyangiitis</p> <p>Re-induction of remission</p> <p>The treatment must be for the re-induction of remission; AND</p> <p>Patient must have previously received and responded to this drug for this condition; AND</p> <p>The treatment must in combination with glucocorticoids; AND</p> <p>Patient must be at risk of end-organ damage or mortality; AND</p> <p>Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.</p> <p>Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.</p> <p>This drug is not PBS-subsidised for maintenance therapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9539
	C9611		Severe active rheumatoid arthritis	Compliance with Authority

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 rheumatoid 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 The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. 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 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. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. 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>	Required procedures - Streamlined Authority Code 9611
	C9640		<p>Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Re-induction of remission The treatment must be for the re-induction of remission; AND Patient must have previously received and responded to this drug for this condition; AND The treatment must in combination with glucocorticoids; AND Patient must be at risk of end-organ damage or mortality; AND Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide. Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology. This drug is not PBS-subsidised for maintenance of remission</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9640

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	C9641		<p>Severe active microscopic polyangiitis                      Re-induction of remission                      The treatment must be for the re-induction of remission; AND                      Patient must have previously received and responded to this drug for this condition; AND                      The treatment must in combination with glucocorticoids; AND                      Patient must be at risk of end-organ damage or mortality; AND                      Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.                      Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.                      This drug is not PBS-subsidised for maintenance therapy.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9641</p>
Romiplostim	C11205		<p>Severe thrombocytopenia                      Initial treatment 2 - New patient                      The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND                      Patient must not have had a splenectomy; AND                      Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; AND                      Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND                      Patient must be unsuitable for splenectomy due to medical reasons; AND                      The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.                      Patient must be aged 18 years or older.                      The following criteria indicate failure to achieve an adequate response 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.                      Where intolerance to treatment with corticosteroid and immunoglobulin therapy 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.                      At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.                      Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.                      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 and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.                      Authority approval will not be given for doses higher than 10 micrograms/kg/week</p>	<p>Compliance with Written Authority Required procedures</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form,</p> <p>(2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,</p> <p>(3) details of a platelet count supporting the diagnosis of ITP, and</p> <p>(4) details of the reason of medical contraindication for surgery and date of assessment.</p> <p>The platelet count must be no more than 4 weeks old at the time of application.</p> <p>Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.</p>	
	C11246		<p>Severe thrombocytopenia</p> <p>Balance of supply or change of therapy within 24 weeks initial treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR</p> <p>Patient must be swapping therapy from eltrombopag to this drug for this condition within the initial 24 weeks of treatment; OR</p> <p>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 to complete 24 weeks treatment; OR</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent 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 available under the above restriction.</p> <p>Patient must be aged 18 years or older.</p> <p>Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.</p>	Compliance with Authority Required procedures
	C11266		<p>Severe thrombocytopenia</p> <p>Initial treatment 1 - New patient</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p>	Compliance with Written Authority Required procedures

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			<p>Patient must have had a splenectomy; AND                      Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy; AND                      Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy; AND                      The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.                      Patient must be aged 18 years or older.                      The following criteria indicate failure to achieve an adequate response 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.                      Where intolerance to treatment with corticosteroid and immunoglobulin therapy 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.                      At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.                      Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.                      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 and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.                      Authority approval will not be given for doses higher than 10 micrograms/kg/week                      The authority application must be made in writing and must include:                      (1) a completed authority prescription form,                      (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,                      (3) details of a platelet count supporting the diagnosis of ITP.                      The platelet count must be no more than 4 weeks old at the time of application.                      Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.</p>	
	C11267		<p>Severe thrombocytopenia                      First Continuing treatment or Re-initiation of interrupted continuing treatment</p>	<p>Compliance with Written Authority Required procedures</p>



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			<p>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;            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; AND            Patient must not have previously received PBS-subsidised continuing treatment with eltrombopag for this condition; AND            The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.            Patient must be aged 18 years or older.            For the purposes of this restriction, a sustained platelet response is defined as:            (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,            AND either of the following:            (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;            OR            (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.            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            Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:            (1) a completed authority prescription form, and            (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and            (3) the most recent platelet count.            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.</p>	
	C11289		<p>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.            Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures

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			<p>For the purpose of this restriction, a continuing response to treatment with drug is defined as:                      (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug                      AND either of the following:                      (b) a platelet count greater than or equal to 50,000 million per L                      OR                      (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.                      The platelet count must be no more than 4 weeks old at the time of application.                      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</p>	
Saquinavir	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
Selexipag	C11193	P11193	<p>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</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			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.	
	C11195	P11195	<p>Pulmonary arterial hypertension (PAH) Initial treatment following dose titration Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR Patient must have WHO Functional Class IV PAH at treatment initiation with this drug; 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 Patient must have completed the dose titration phase; 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. 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. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. 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.</p>	Compliance with Authority Required procedures
	C11241	P11241	<p>Pulmonary arterial hypertension (PAH) Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021; AND Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug; AND</p>	Compliance with Authority Required procedures

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			<p>Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR                      Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug; AND                      Patient must not have developed disease progression while receiving treatment with this drug for this condition; 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                      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.                      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, epoprostenol, iloprost, riociguat.                      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.                      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.</p>	
	C11261	P11261	<p>Pulmonary arterial hypertension (PAH)                      Initial treatment - dose titration                      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                      Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>Patient must have WHO Functional Class IV PAH at treatment initiation with this drug; AND The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks; 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. 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, eproprostamol, iloprost, riociguat. 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.</p>	
Sevelamer	C5530		<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>	Compliance with Authority Required procedures - Streamlined Authority Code 5530
	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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9762

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			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.	
Sildenafil	C10228		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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, eprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10234		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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, eprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.	Compliance with Authority Required procedures
	C10304		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension	Compliance with Written Authority Required procedures

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			<p>(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 II PAH, or WHO Functional Class III PAH; AND  The treatment must be the sole PBS-subsidised PAH agent for this condition.  The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.  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.  Applications for authorisation must be in writing and must include:  (1) a completed authority prescription form; and  (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:  (i) RHC composite assessment; and  (ii) ECHO composite assessment; and  (iii) 6 Minute Walk Test (6MWT).  Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:  (1) RHC plus ECHO composite assessments;  (2) RHC composite assessment plus 6MWT;  (3) RHC composite assessment only.  In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:  (1) ECHO composite assessment plus 6MWT;  (2) ECHO composite assessment only.  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 provided with the authority application.  Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.  The test results provided must not be more than 2 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.</p>	

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	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 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
	C11319		<p>Pulmonary arterial hypertension (PAH)                      Initial 1 (starting dual therapy in an untreated patient for the first time)                      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 dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, but only for WHO Functional Class IV PAH.                      Must be treated by a physician with expertise in the management of PAH, with this authority application</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>to be completed by the physician with expertise in PAH.</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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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. 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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11338		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (starting dual therapy in a treated patient for the first time)</p> <p>The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR</p>	Compliance with Authority Required procedures

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			<p>The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated; 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 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.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>	
	C11340		<p>Pulmonary arterial hypertension (PAH)</p> <p>'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised</p> <p>Patient must have been receiving non-PBS subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with an endothelin receptor antagonist, where each agent was non-PBS subsidised, prior to 1 October 2020; OR</p> <p>Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND</p> <p>The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR</p> <p>The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; 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 failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (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 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, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid 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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>Applications for authorisation must be lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p>	

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			<p>(1) ECHO composite assessment plus 6MWT;                      (2) ECHO composite assessment only.                      Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.                      Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.                      A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.                      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>	
	C11350		<p>Pulmonary arterial hypertension (PAH)                      Continuing treatment (dual therapy)                      Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; 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.                      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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.                      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.                      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
	C11352		<p>Pulmonary arterial hypertension (PAH)                      Initial 3 (dual therapy - change)                      Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; AND                      The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.</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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>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>	
Sirolimus	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
	C9914		<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 9914
Sofosbuvir with velpatasvir	C5969		<p>Chronic hepatitis C infection</p> <p>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND</p> <p>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</p> <p>The treatment must be limited to a maximum duration of 12 weeks.</p>	Compliance with Authority Required procedures
Sofosbuvir with velpatasvir and voxilaprevir	C10248		<p>Chronic hepatitis C infection</p> <p>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND</p> <p>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</p> <p>The treatment must be limited to a maximum duration of 12 weeks.</p> <p>The application must include details of the prior treatment regimen containing an NS5A inhibitor.</p>	Compliance with Authority Required procedures
Sucroferric oxyhydroxide	C5530		<p>Hyperphosphataemia</p> <p>Initiation and stabilisation</p> <p>The condition must not be adequately controlled by calcium; AND</p> <p>Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR</p> <p>The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5530

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			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
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
	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	C10228		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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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
	C10234		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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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>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>	
	C10304		<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 II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. 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. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</p>	Compliance with Written Authority Required procedures

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			<p>(1) RHC plus ECHO composite assessments;                      (2) RHC composite assessment plus 6MWT;                      (3) RHC composite assessment only.                      In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:                      (1) ECHO composite assessment plus 6MWT;                      (2) ECHO composite assessment only.                      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 provided with the authority application.                      Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.                      The test results provided must not be more than 2 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.</p>	
	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</p>	Compliance with Authority Required procedures



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			<p>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>	
	C11319		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (starting dual therapy in an untreated patient for the first time)</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 dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, but only for WHO Functional 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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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>Applications for authorisation must be in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</p> <p>(1) RHC plus ECHO composite assessments;</p> <p>(2) RHC composite assessment plus 6MWT;</p> <p>(3) RHC composite assessment only.</p>	Compliance with Written Authority Required procedures

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			<p>In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</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 provided with the authority application.</p> <p>Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>The test results provided must not be more than 2 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>	
	C11338		<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (starting dual therapy in a treated patient for the first time)</p> <p>The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR</p> <p>The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated;</p> <p>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 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.</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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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>	
	C11340		<p>Pulmonary arterial hypertension (PAH)</p> <p>'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised</p> <p>Patient must have been receiving non-PBS subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with an endothelin receptor antagonist, where each agent was non-PBS subsidised, prior to 1 October 2020; OR</p> <p>Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021; AND</p> <p>The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR</p> <p>The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated; 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 if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (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 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, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid 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>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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.</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</p>	Compliance with Written Authority Required procedures

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			<p>pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>Applications for authorisation must be lodged either electronically or via mail/postal service and include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:</p> <p>(i) RHC composite assessment; and</p> <p>(ii) ECHO composite assessment; and</p> <p>(iii) 6 Minute Walk Test (6MWT).</p> <p>Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</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 circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <p>(1) ECHO composite assessment plus 6MWT;</p> <p>(2) ECHO composite assessment only.</p> <p>Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.</p> <p>Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.</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>	
	C11350		<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment (dual therapy)</p> <p>Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply; 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 prostanoid, (ii) one</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>phosphodiesterase-5 inhibitor.            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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.            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.            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>	
	C11352		<p>Pulmonary arterial hypertension (PAH)            Initial 3 (dual therapy - change)            Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing; 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.            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; a prostanoid is one of: (f) epoprostenol, (g) iloprost.            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.            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
Teduglutide	C9515		<p>Type III Short bowel syndrome with intestinal failure            Initial treatment or initial grandfather 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;            OR            Patient must have received PBS-subsidised treatment with this drug for this condition as a grandfathered patient; AND            Patient must have received insufficient therapy with this drug under the initial or grandfather 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
	C9569		<p>Type III Short bowel syndrome with intestinal failure            Initial treatment</p>	Compliance with Written Authority Required procedures

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			<p>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 condition.                      Baseline is the mean number of days of parenteral support per week over the four weeks immediately prior to initiating treatment with teduglutide under the PBS initial treatment restriction or four weeks immediately prior to initiating treatment with non-PBS subsidised teduglutide for grandfathered patients.                      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.                      Baseline number of days of parenteral support should be documented in the patient's medical records.                      The authority application must be made in writing and must include:                      (1) a completed authority prescription form; and                      (2) a completed Short bowel syndrome with intestinal failure form; and                      (3) details of baseline mean number of days on parenteral support per week for 4 consecutive weeks immediately preceding this application; and                      (4) documented duration in months of prior dependence on parenteral support.</p>	
	C9687		<p>Type III Short bowel syndrome with intestinal failure                      Initial treatment - Grandfathered patients                      Must be treated by a gastroenterologist; OR                      Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.                      Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2019; AND                      Patient must have short bowel syndrome with intestinal failure following major surgery; AND                      Patient must have had a history of dependence on parenteral support for at least 12 months prior to initiating non-PBS subsidised treatment with this drug for this condition; AND                      Patient must have received a stable parenteral support regimen for at least 3 days per week in the 4 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition; AND                      Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years; AND                      Patient must have achieved a treatment response if the patient has been on non-PBS subsidised therapy with this drug for more than 12 months.                      Baseline is the mean number of days of parenteral support per week over the 4 weeks immediately prior to initiating treatment with non-PBS subsidised teduglutide for grandfathered patients.                      A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.</p> <p>A patient has met the criteria for treatment response when there is a reduction in the mean number of days of parenteral support of at least 1 day per week since initiating non-PBS subsidised treatment, or where a patient has completely ceased treatment with parenteral support for a period of at least 4 consecutive weeks prior to application for PBS-subsidised treatment.</p> <p>The number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs between commencement of non-PBS subsidised teduglutide and application for PBS-subsidised treatment.</p> <p>The authority application must be made in writing and must include:</p> <ol style="list-style-type: none"> <li>(1) a completed authority prescription form; and</li> <li>(2) a completed Short bowel syndrome with intestinal failure Grandfather PBS Authority Application - Supporting Information Form; and</li> <li>(3) details of non-PBS subsidised teduglutide treatment start date; and</li> <li>(4) details of the mean number of days on parenteral support per week for 4 consecutive weeks prior to initiating non-PBS subsidised therapy; and</li> <li>(5) documented duration in months of dependence on parenteral support prior to initiating non-PBS subsidised treatment; and</li> <li>(6) details of response to teduglutide treatment if patient has received 12 or more months of non-PBS subsidised treatment.</li> </ol> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For patients who have been on this drug for less than 12 months, the maximum number of repeats that will be approved will be for an amount equivalent to an initial 12 month supply of PBS and non-PBS subsidised treatment.</p> <p>For patients who have been on this drug for more than 12 months, a maximum of 5 repeats will be approved.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the First continuing treatment criteria.</p>	
	C9740		<p>Type III Short bowel syndrome with intestinal failure Subsequent continuing treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have received PBS-subsidised first-continuing treatment with this drug for this condition and achieved a treatment response in the preceding treatment period; OR Patient must have received PBS-subsidised recommencement of treatment following a trial cessation period and not have previously experienced a failure to respond to treatment with this drug for this condition. Treatment response For applications for subsequent continuing treatment, treatment response is when there was a reduction in the mean number of days of parenteral support of at least 1 day per week since the last assessment</p>	Compliance with Written Authority Required procedures

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			<p>for PBS-subsidised treatment, OR where a patient has completely ceased treatment with parenteral support for a period of at least 4 consecutive weeks. The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period Treatment failure For applications for subsequent continuing treatment, failure of treatment is defined as an increase in the mean number of days per week of parenteral support requirements of at least 1 day per week over the preceding 4 week period compared to the last assessment for PBS-subsidised treatment of parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs. Patients who experience failure of treatment must permanently discontinue treatment. Treatment stability Patients who neither demonstrate a treatment response nor a treatment failure since the last assessment for PBS-subsidised treatment are considered to have a stable parenteral support regimen, defined as the same mean number of days of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the 4 weeks preceding treatment period, where the number of days is greater than zero and the mean number of days of parenteral support is less than baseline. Patients with a stable parenteral support regimen over 6 months must undertake a trial cessation period. Patients who have re-commenced after a trial cessation period are exempt from further trial cessation. Trial cessation period Patients who demonstrate a stable frequency of mean days per week of parenteral support in a 6-month period commencing after the initial 12 months of treatment with this drug for this condition are required to undertake a trial of treatment cessation. Patients who have re-commenced after a trial cessation period are exempt from further trial cessation. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure Form; and (3) details of the mean number of days reduction of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the preceding treatment period or confirmation the patient has had 4 consecutive weeks without parenteral support (if applicable); and (4) the current mean number of days per week of parenteral support over the preceding 4 week period.</p>	
	C9793		<p>Type III Short bowel syndrome with intestinal failure First 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; OR Patient must have received PBS-subsidised treatment with this drug for this condition as a grandfathered patient; 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 reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline.</p> <p>Baseline is the mean number of days of parenteral support per week over the four weeks immediately prior to initiating treatment with teduglutide under the PBS initial treatment restriction or four weeks immediately prior to initiating treatment with non-PBS subsidised teduglutide for grandfathered patients. The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period</p> <p>Treatment failure For applications for first continuing treatment, failure of treatment is defined as no change compared to baseline in the mean number of days per week in parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs. Patients who experience failure of treatment must permanently discontinue treatment. Current mean number of days of parenteral support should be documented in the patient's medical records.</p> <p>The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure Form; and (3) details of the mean number of days reduction of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs from baseline; and (4) the current mean number of days per week of parenteral support over the preceding 4 week period.</p>	
	C9829		<p>Type III Short bowel syndrome with intestinal failure Recommencement of treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have received PBS-subsidised treatment with this drug for this condition; AND Patient must have undertaken a trial cessation period due to experiencing a stable parenteral support regimen in the first continuing or subsequent continuing treatment phase, and not due to a treatment failure; AND Patient must have experienced deterioration during a trial cessation period. Trial cessation period Patients who demonstrate a stable frequency of mean days per week of parenteral support in a 6-month period commencing after the initial 12 months of treatment with this drug for this condition are required to undertake a trial of treatment cessation. Patients who have re-commenced after a trial cessation period are exempt from further trial cessation. Deterioration during the trial cessation period includes an increase in parenteral support frequency of more than or equal to one day per week from the pre-cessation level, or other clinical parameters suggestive of deterioration including changes in renal function or urinary sodium levels or changes in body weight.</p> <p>The authority application must be made in writing and must include: (1) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

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			(2) a completed Short bowel syndrome with intestinal failure Form; and (3) details of the reason for recommencement after trial cessation; and (4) the current mean number of days per week of parenteral support over the preceding 4 week period (5) details of completion of the trial cessation period including the start and end date.	
Tenofovir	C6980	P6980	Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have detectable HBV DNA; AND The treatment must be the sole PBS-subsidised therapy for this condition. 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 6980
	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	Compliance with Authority Required procedures - Streamlined Authority Code 6992

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			(ii) liver biopsy; AND The treatment must be the sole PBS-subsidised therapy for this condition.	
	C6998	P6998	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 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 naïve	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Tezacaftor with ivacaftor and ivacaftor	C9880		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	Compliance with Written Authority Required procedures

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			<p>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> <p>Patient must be 12 years of age or older.</p> <p>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</p> <p>Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.</p> <p>For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.</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> <ol style="list-style-type: none"> <li>(1) a completed authority prescription form; and</li> <li>(2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and</li> <li>(3) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and</li> <li>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</li> <li>(5) height and weight measurements at the time of application; and</li> <li>(6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6</li> </ol>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			months.	
	C9961		<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 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 be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; 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. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. 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 form; and (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for</p>	Compliance with Written Authority Required procedures

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			<p>the F508del mutation on the CFTR gene; and                      (4) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and                      (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and                      (6) height and weight measurements at the time of application; and                      (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.                      For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV1 and hospitalisation dates prior to initiating treatment (where available) should be provided.</p>	
	C10064		<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 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.                      The patient must be registered in the Australian Cystic Fibrosis Database Registry.                      Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.                      For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.                      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,</p>	Compliance with Written Authority Required procedures

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			<p>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 form; and</p> <p>(2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and</p> <p>(3) a copy of the pathology report detailing the molecular testing for the patient having at least one RF mutation on the CFTR gene; and</p> <p>(4) the result of a FEV<sub>1</sub> measurement performed within a month prior to the date of application. Note: FEV<sub>1</sub> must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV<sub>1</sub> is measured; and</p> <p>(5) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(6) height and weight measurements at the time of application; and</p> <p>(7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the-home) in the previous 12 months.</p> <p>For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV<sub>1</sub> and hospitalisation dates prior to initiating treatment (where available) should be provided.</p>	
	C10069		<p>Cystic fibrosis - one residual function (RF) mutation</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> <p>Patient must be 12 years of age or older.</p> <p>Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.</p> <p>Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.</p>	Compliance with Written Authority Required procedures

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			<p>For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.</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 form; and</p> <p>(2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and</p> <p>(3) the result of a FEV<sub>1</sub> measurement performed within a month prior to the date of application. Note: FEV<sub>1</sub> must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV<sub>1</sub> is measured; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and</p> <p>(5) height and weight measurements at the time of application; and</p> <p>(6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.</p>	
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
Tipranavir	C5764		<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>The treatment must be co-administered with 200 mg ritonavir twice daily, AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5764



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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>	
Tocilizumab	C8627		<p>Severe active rheumatoid arthritis</p> <p>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 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 available under the above restriction.</p>	Compliance with Authority Required procedures
	C8635		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less 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 received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; 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>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, 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>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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>	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>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>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> <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(s); and</p> <p>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.</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>	
	C8636		<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (re-commencement 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 recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 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. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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 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. 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>	
	C8637		Severe active rheumatoid arthritis Continuing treatment	Compliance with Written Authority Required procedures

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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 per continuing treatment course authorised under this restriction.                      Patient must be aged 18 years or older.                      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 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 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(s); and                      (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      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 provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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.	
	C8638		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
	C8709		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 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 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 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 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must	Compliance with Written Authority Required procedures

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			<p>include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND                      Patient must not receive more than 16 weeks of treatment under this restriction.                      Patient must be aged 18 years or older.                      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.                      The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.                      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.                      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.                      The following criteria indicate failure to achieve an adequate response 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 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).                      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.                      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.                      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.                      The authority application must be made in writing and must include:                      (1) a completed authority prescription form(s); and                      (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.                      It is recommended that an assessment of a patient's response is conducted following a minimum of 12</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. 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>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> <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>	
	C9380		<p>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.</p>	Compliance with Authority Required procedures
	C9384		<p>Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply 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 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.</p>	Compliance with Authority Required procedures
	C9386		<p>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</p>	Compliance with Authority Required procedures

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			(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.	
	C9407		<p>Severe active juvenile idiopathic 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 recently approved PBS-subsidised biological medicine for this condition; OR 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 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 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. 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 measures of joint count must be no more than 4 weeks old at the time of this 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 prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. 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. 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 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</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C9494		<p>Severe active juvenile idiopathic 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 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. 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). 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. 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. 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 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. 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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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.</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. 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 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; 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. Patient must be aged 18 years or older. 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). 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. The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

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			<p>(1) completed authority prescription form(s); and                      (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.                      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.                      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.                      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.                      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>	
	C9496		<p>Severe active juvenile idiopathic 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 have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; 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 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                      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</p>	Compliance with Written Authority Required procedures

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			<p>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 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; 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 trialed, 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 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>	

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			<p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. 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 reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
	C10532		<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 (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: 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); 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 authority application must be made in writing and must include:</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;</p> <p>(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 two infusions (one month's supply). 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 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>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>	
	C10535		<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 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</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>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 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 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>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 Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;</p> <p>(ii) details of prior treatment including dose and duration of treatment;</p> <p>(iii) pathology reports detailing CRP and platelet count where appropriate.</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 prescription form must be completed 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 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>	



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	C10536		<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; 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>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"> <li>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>- 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).</li> </ul> <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>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 submitted with the initial treatment application.</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 Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.</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 two infusions (one month's supply). A separate authority prescription form must be completed 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</p>	Compliance with Written Authority Required procedures

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			<p>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 approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
	C10541		<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>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:</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>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</p>	Compliance with Written Authority Required procedures

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			<p>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>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 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. 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>	
	C10542		<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). 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 submitted with the initial treatment application. The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

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			<p>(1) completed authority prescription form(s); and                      (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.                      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.                      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 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 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 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.                      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>	
	C10545		<p>Severe active juvenile idiopathic arthritis                      Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 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; or (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</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>All measures of joint count must be no more than 4 weeks old at the time of this application. 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 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:</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>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>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 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>	
	C10567		<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (retial or recommencement 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</p>	Compliance with Written Authority Required procedures

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			<p>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"> <li>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</li> <li>- 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).</li> </ul> <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>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 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:</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.</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 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. 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 approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</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</p>	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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 (retial 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>	Required procedures
	C10571		<p>Systemic juvenile idiopathic arthritis</p> <p>Balance of supply - Continuing treatment</p> <p>Patient must have received insufficient therapy with this drug for this condition under the 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 therapy available under 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>	Compliance with Authority Required procedures
	C10616		<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</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 not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR</p> <p>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; or (ii) 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</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>	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>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 another DMARD 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>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 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 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 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>	
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            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 treatment that would otherwise extend the initial treatment period.            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.            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</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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</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 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 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 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 2 doses to be administered at weeks 0 and 8 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) two completed authority prescription forms; 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>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.</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 (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.</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>	

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			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.	
	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 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 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 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</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>criterion, if relevant; and (iv) the date of the most recent clinical assessment. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (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. 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 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 treatment that would otherwise extend the initial treatment period. 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 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 necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. 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</p>	

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			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. 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.	
Valaciclovir	C5975		Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5975
	C9267		Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	Compliance with Authority Required 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	C9682		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)]. 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	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 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.</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.            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 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.            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 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.            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.</p>	

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			Details of the accepted toxicities including severity can be found on the Department of Human Services website.	
	C9683		<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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; 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 the response. 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. 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 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>	Compliance with Authority Required procedures
	C9708		<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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</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>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> <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 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</p>	

Schedule 3 Circumstances and purposes

Clause 1

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements—Part of Circumstances
			<p>intestine disease or is an ostomy patient. 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. 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 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 necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. 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. 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 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. The 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. 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 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.</p>	
	C9738		<p>Moderate to severe ulcerative colitis Balance of supply Must be treated by a gastroenterologist (code 87); OR</p>	Compliance with 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 [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 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 continuing treatment restriction to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 3 doses 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; AND</p> <p>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.</p>	
	C9739		<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>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>	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 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>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 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>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
	C9771		<p>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 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.</p>	Compliance with Authority Required procedures
	C9792		<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 OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. 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 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>	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 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 of initial treatment must be 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].                      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 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.                      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 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.                      Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p>	
	C9796		<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)];</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older.</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 not receive more than 24 weeks of treatment 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 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</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>If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.</p> <p>The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.</p> <p>Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, 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</p>	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. 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. 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>	
	C9815		<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 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</p>	Compliance with Written Authority Required procedures



Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<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 to the Department of Human Services no later than 4 weeks from the date that course was ceased.</p> <p>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 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 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 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 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>	
	C9825		<p>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)];</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>OR</p> <p>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</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 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 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; 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</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			<p>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> <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 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>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. 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</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
Zoledronic acid	C5605		<p>Bone metastases</p> <p>The condition must be due to breast cancer.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5605
	C5703		<p>Bone metastases</p> <p>The condition must be due to castration-resistant prostate cancer.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5703
	C5704		Hypercalcaemia of malignancy	Compliance with Authority

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements— Part of Circumstances
			Patient must have a malignancy refractory to anti-neoplastic therapy.	Required procedures - Streamlined Authority Code 5704
	C5735		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5735
	C9268		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9268
	C9304		Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9304
	C9317		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9317
	C9328		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9328

## Schedule 4—HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic

Note: See section 17.

### 1 HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic

The following table sets out pharmaceutical items with modified prescription circumstances during the COVID-19 pandemic.

<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>		
<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>
Abatacept	Powder for I.V. infusion 250 mg	Injection
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection
Ambrisentan	Tablet 5 mg	Oral
Ambrisentan	Tablet 10 mg	Oral
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral
Bosentan	Tablet 125 mg (as monohydrate)	Oral
Dornase alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection
Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium)	Injection
Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation

**Schedule 4** HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic

Clause 1

**Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic**

<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>
Infliximab	Powder for I.V. infusion 100 mg	Injection
Ivacaftor	Sachet containing granules 50 mg	Oral
Ivacaftor	Sachet containing granules 75 mg	Oral
Ivacaftor	Tablet 150 mg	Oral
Lenalidomide	Capsule 5 mg	Oral
Lenalidomide	Capsule 10 mg	Oral
Lenalidomide	Capsule 15 mg	Oral
Lenalidomide	Capsule 25 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral
Macitentan	Tablet 10 mg	Oral
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth
Mepolizumab	Powder for injection 100 mg	Injection
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen	Injection
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection
Pomalidomide	Capsule 3 mg	Oral
Pomalidomide	Capsule 4 mg	Oral
Riociguat	Tablet 500 micrograms	Oral
Riociguat	Tablet 1 mg	Oral
Riociguat	Tablet 1.5 mg	Oral
Riociguat	Tablet 2 mg	Oral
Riociguat	Tablet 2.5 mg	Oral
Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection
Sildenafil	Tablet 20 mg (as citrate)	Oral
Tadalafil	Tablet 20 mg	Oral
Tezacaftor with	Pack containing 28 tablets tezacaftor 100 mg with	Oral

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**Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic**

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<b>Listed drug</b>	<b>Form</b>	<b>Manner of administration</b>
ivacaftor and ivacaftor	ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection
Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection
Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection
Vedolizumab	Powder for injection 300 mg	Injection

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## **Schedule 5—Repeals**

### ***National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010)***

#### **1 The whole of the instrument**

Repeal the instrument.