National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024

PB 31 of 2024

made under sections 85, 85A, 99 and 100 of the

National Health Act 1953

Compilation No. 8

Compilation date: 1 December 2024

Includes amendments: F2024L01543

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* that shows the text of the law as amended and in force on 1 December 2024 (the ***compilation date***).

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

Uncommenced amendments

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

Application, saving and transitional provisions for provisions and amendments

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

Editorial changes

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

Modifications

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

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*.

(2) This instrument may also be cited as PB 31 of 2024.

3 Authority

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

4 Simplified outline

This instrument makes a special arrangement for providing that an adequate supply of pharmaceutical benefits will be available to persons who are receiving treatment for cancer or cancer-related conditions.

This instrument provides for medical practitioners to prescribe chemotherapy drugs in doses tailored to the needs of individual patients, rather than prescribing specific pharmaceutical benefits. Suppliers are to supply the prescribed doses of those drugs, with the supply being made from chemotherapy pharmaceutical benefits.

This instrument also deals with payments for supplies of doses of chemotherapy drugs, with the amount payable being based on the cheapest combination of chemotherapy pharmaceutical benefits that could be used to provide the prescribed doses of drugs.

This instrument also provides for some kinds of prescription, supply and payment in relation to other pharmaceutical benefits used in treatment for cancer or cancer-related conditions.

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).

5 Definitions

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

Note 3: A reference to an approved supplier or an approved hospital authority includes a reference to an HSD hospital authority within the meaning of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*: see section 11 of that instrument.

In this instrument:

Act means the *National Health Act 1953*.

active ingredient, in relation to a chemotherapy drug, means a drug that is mentioned in the name of the chemotherapy drug.

Note: A chemotherapy drug may be a medicinal preparation containing multiple drugs (see the definition of ***listed drug*** in Part VII of the Act).

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.

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.

authorised prescriber has the meaning given by section 6.

authority prescription means a prescription that has been authorised:
(a) in accordance with section 30 of the Regulations as modified by this instrument; or
(b) in accordance with section 19 of the Listing Instrument as modified by this instrument.

chemotherapy drug means a listed drug that is mentioned in Part 1 of Schedule 1.

Note: Each chemotherapy drug is also mentioned in Part 2 of Schedule 1.

chemotherapy pharmaceutical benefit means a pharmaceutical benefit that is mentioned in Part 1 of Schedule 1.

chemotherapy prescription has the meaning given by subsection 11(1).

circumstances code means the letter "C" followed by a number.

compounder means an entity (including a person, pharmacy, hospital or a body corporate) who undertakes and is responsible for the compounding of doses of chemotherapy drugs.

compounder ID means the identification number allocated to a compounder by the Chemotherapy Compounding Payment Scheme Administration Agency in respect of a compounding site.

Note: At the commencement of this instrument, Australian Healthcare Associates Pty Ltd was the Chemotherapy Compounding Payment Scheme Administration Agency.

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

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

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

diluent fee means an amount of $5.95.

dispensed price:

(a) for a special arrangement supply of a dose of a chemotherapy drug by an approved pharmacist or an approved medical practitioner—has the meaning given by section 31; and

(b) for a special arrangement supply of a dose of a chemotherapy drug by an approved hospital authority of a private hospital—has the meaning given by section 33; and

(c) for a special arrangement supply of a dose of a chemotherapy drug by an approved hospital authority of a public hospital—has the meaning given by section 34; and

(d) for a special arrangement supply of a related pharmaceutical benefit—has the meaning given by section 35.

dispensing fee means an amount of $8.67.

distribution fee means an amount of $30.05.

dose, of a chemotherapy drug, means a quantity of the drug for a single treatment of a patient that is made from one or more chemotherapy pharmaceutical benefits.

electronic medication chart prescription means a medication chart prescription prepared, in electronic form, in a software system that is used for prescribing and recording the administration of medicines to persons receiving treatment in, at or from a hospital.

eligible patient has the meaning given by section 7.

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

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

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

medication chart has a meaning affected by subsection 20(1).

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

National Health Reform Agreement has the same meaning as in the *Federal Financial Relations Act 2009*.

pack quantity of a listed brand of a pharmaceutical item has the same meaning as in Part VII of the Act.

participating hospital authority means an approved hospital authority of a public hospital that is participating in a Pharmaceutical Reform Arrangement within the meaning of the National Health Reform Agreement.

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

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

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

preparation fee means an amount of $90.13.

pricing quantity of a listed brand of a 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 Benefits) Regulations 2017*.

related pharmaceutical benefit means a pharmaceutical benefit mentioned in Schedule 2.

restricted drug has the meaning given by subsection 12(1).

single unit ex-manufacturer price, for a chemotherapy pharmaceutical benefit that is a listed brand of a pharmaceutical item, means the approved ex-manufacturer price for the chemotherapy pharmaceutical benefit divided by the pricing quantity for the chemotherapy pharmaceutical benefit.

Note: This price is for the form of the chemotherapy pharmaceutical benefit mentioned in Part 1 of Schedule 1, which is not necessarily the same quantity as the quantity in a manufacturer's pack.

For example, if a chemotherapy pharmaceutical benefit has a form of "Injection 500 mg in 10 mL", and the pricing quantity is 5 units of "Injection 500 mg in 10 mL", the approved ex-manufacturer price would be divided by 5 to obtain the single unit ex-manufacturer price.

special arrangement supply has the meaning given by section 10.

TGA-licensed compounder means a compounder who holds a licence issued under the *Therapeutic Goods Act 1989* that authorises the aseptic compounding of sterile chemotherapy drugs.

TGA-licensed compounding fee means an amount of $20.

variation code means the letter "V" followed by a number.

6 Definition of *authorised prescriber*

(1) A medical practitioner is an ***authorised prescriber*** for a chemotherapy drug.

(2) A medical practitioner is an ***authorised prescriber*** for a related pharmaceutical benefit.

7 Definition of *eligible patient*

(1) A person is an ***eligible patient*** for a chemotherapy drug if:
  (a) the person is, or is to be treated as, an eligible person; and
  (b) a dose of the drug is or will be prescribed to the person for the purposes of treatment for cancer or a cancer-related condition.

(2) A person is an ***eligible patient*** for a related pharmaceutical benefit if:
  (a) the person is, or is to be treated as, an eligible person; and
  (b) the benefit is or will be prescribed to the person for the purposes of treatment for cancer or a cancer-related condition.

8 Application of Act and instruments in relation to special arrangement supplies to patients receiving treatment from hospitals

(1) In the application of Part VII of the Act, and regulations or other instruments made for the purposes of that Part, to special arrangement supplies, a reference to a person receiving treatment in or at an approved hospital is taken to include a reference to a person receiving treatment from an approved hospital.

(2) 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 a hospital is taken to include a reference to an approved hospital authority supplying doses of chemotherapy drugs or related pharmaceutical benefits to patients receiving treatment from a hospital.

9 Application of Act and instruments in relation to chemotherapy prescriptions and special arrangement supplies of doses of chemotherapy drugs

(1) Subject to this instrument, a reference in Part VII of the Act, or regulations or other instruments made for the purposes of that Part, to a prescription for the supply of a pharmaceutical benefit is taken to include a reference to a chemotherapy prescription.

(2) Subject to this instrument, a reference in Part VII of the Act, or regulations and other instruments made for the purposes of that Part, to a supply of a pharmaceutical benefit is taken to include a special arrangement supply of a dose of a chemotherapy drug.

Part 2—Special arrangement supplies

Division 1—Preliminary

10 Definition of *special arrangement supply*

Doses of chemotherapy drugs supplied by approved pharmacists

(1) A supply of a dose of a chemotherapy drug to a person is a ***special arrangement supply*** of the dose if:
  (a) the person is an eligible patient for the drug; and
  (b) the dose is supplied by an approved pharmacist; and
  (c) the dose is supplied on the basis of a chemotherapy prescription written by an authorised prescriber for the drug in accordance with Division 2.

Doses of chemotherapy drugs supplied by approved medical practitioners

(2) A supply of a dose of a chemotherapy drug to a person is a ***special arrangement supply*** of the dose if:
  (a) the person is an eligible patient for the drug; and
  (b) the dose is supplied by an approved medical practitioner; and
  (c) the dose is supplied on the basis of a chemotherapy prescription written by an authorised prescriber for the drug in accordance with Division 2; and
  (d) the prescription is not a medication chart prescription.

Doses of chemotherapy drugs supplied by private hospitals

(3) A supply of a dose of a chemotherapy drug to a person is a ***special arrangement supply*** of the dose if:
  (a) the person is an eligible patient for the drug; and
  (b) the dose is supplied by an approved hospital authority of a private hospital; and
  (c) the dose is supplied on the basis of a chemotherapy prescription written:
    (i) when the person was receiving medical treatment at or from a private hospital; and
    (ii) by an authorised prescriber for the drug in accordance with Division 2.

Doses of chemotherapy drugs supplied by public hospitals

(4) A supply of a dose of a chemotherapy drug to a person is a ***special arrangement supply*** of the dose if:
  (a) the person is an eligible patient for the drug; and
  (b) the dose is supplied by a participating hospital authority; and
  (c) the dose is supplied on the basis of a chemotherapy prescription written:

(i) when the person was receiving medical treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge; and

(ii) by an authorised prescriber for the drug in accordance with Division 2.

(5) A supply of a dose of the chemotherapy drug trastuzumab to a person is a ***special arrangement supply*** of the dose if:

(a) the person is an eligible patient for the drug; and

(b) the dose is supplied by an approved hospital authority of a public hospital that is not a participating hospital authority; and

(c) the dose is supplied on the basis of a prescription written:

(i) when the person was receiving medical treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge; and

(ii) by an authorised prescriber for the drug in accordance with Division 2; and

(d) the prescription is not a medication chart prescription.

Related pharmaceutical benefits

(6) A supply of a related 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 a participating hospital authority; and

(c) the benefit is supplied on the basis of a prescription written:

(i) when the person was receiving medical treatment at or from a public hospital as a non-admitted patient, day admitted patient or patient on discharge; and

(ii) by an authorised prescriber for the benefit; and

(iii) if the benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act—in circumstances determined by subsection 12(3) of this instrument.

Division 2—Prescribing doses of chemotherapy drugs and related pharmaceutical benefits

11 Prescribing chemotherapy drugs

(1) Subject to this Division, an authorised prescriber for a chemotherapy drug is authorised to write a prescription (a ***chemotherapy prescription***) for the special arrangement supply of a dose of the drug.

(2) This section applies in addition to authorisations to write prescriptions under section 88 of the Act.

12 Prescription circumstances—general

Chemotherapy drugs

(1) A chemotherapy drug is a ***restricted drug*** if there are one or more circumstances codes mentioned in the column of the table in Part 1 of Schedule 1 headed "Circumstances" in relation to each chemotherapy pharmaceutical benefit that has the chemotherapy drug.

Note: Different chemotherapy pharmaceutical benefits having the same drug may have different circumstances codes. For the purposes of this subsection, it does not matter which circumstances code is mentioned.

(2) A chemotherapy prescription for a dose of a restricted drug may only be written in circumstances mentioned in the column of the table in Part 1 of Schedule 3 headed "Circumstances and Purposes" in relation to any of the circumstances codes that relate to chemotherapy pharmaceutical benefits that have the drug.

Related pharmaceutical benefits

(3) For the purposes of paragraphs 85(7)(a) and (b) of the Act, if a circumstances code is mentioned in the column of the table in Schedule 2 headed "Circumstances" in relation to a related pharmaceutical benefit:

(a) the pharmaceutical benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act; and

(b) the circumstances mentioned in the column of the table in Part 1 of Schedule 3 headed "Circumstances and Purposes" in relation to the circumstances code are circumstances in which a prescription for a special arrangement supply of the pharmaceutical benefit may be written.

Application of this section

(4) This section applies in addition to section 13 of the Listing Instrument.

13 Prescription circumstances—authority required procedures

Restricted drugs

(1) Subsection (3) applies to a chemotherapy prescription for a dose of a restricted drug if the circumstances mentioned in Part 1 of Schedule 3 that apply to the writing of the prescription include:
  (a) Compliance with Authority Required procedures; or
  (b) Compliance with Written Authority Required procedures.

Related pharmaceutical benefits

(2) Subsection (3) applies to a prescription for a special arrangement supply of a related pharmaceutical benefit if the circumstances mentioned in Part 1 of Schedule 3 (if any) in which the prescription is written include:
  (a) Compliance with Authority Required procedures; or
  (b) Compliance with Written Authority Required procedures.

Modified application of Listing Instrument

(3) Section 19 of the Listing Instrument applies to the prescription as if:
  (a) a reference to Part 1 of Schedule 4 to that instrument were a reference to Part 1 of Schedule 3 to this instrument; and
  (b) a reference to an authorised prescriber were a reference to an authorised prescriber within the meaning of this instrument.

14 Maximum amount—chemotherapy drugs

(1) This section determines the maximum amount of a chemotherapy drug that an authorised prescriber may, in one chemotherapy prescription, direct to be supplied in a dose of the drug.

(2) If only one amount is mentioned in the column of the table in Part 2 of Schedule 1 headed "Maximum Amount" (the ***maximum amount column***) in relation to a chemotherapy drug, that amount is the maximum amount of the chemotherapy drug for all purposes.

(3) If more than one amount is mentioned in the maximum amount column in relation to a chemotherapy drug, then:
  (a) if a purposes code is mentioned in the column of the table headed "Purposes" in relation to an amount—that amount is the maximum amount of the chemotherapy drug for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code; and
  (b) if no purposes code is mentioned in the column in relation to an amount—that amount is the maximum amount for all purposes other than purposes to which paragraph (a) applies.

(4) For a chemotherapy drug mentioned in column 1 of an item of the following table:

(a) an amount mentioned in the maximum amount column in relation to the chemotherapy drug is the maximum amount, of the active ingredient mentioned in column 2 of the item of the following table, that an authorised prescriber may direct to be supplied in a dose of the chemotherapy drug; and

(b) a reference in this instrument to the maximum amount of the chemotherapy drug is taken to be a reference to the maximum amount of the active ingredient.

Maximum amounts for chemotherapy drugs with multiple active ingredients

Item	Column 1 Chemotherapy drug	Column 2 Active ingredient
1	daunorubicin with cytarabine	daunorubicin
2	nivolumab with relatlimab	nivolumab

14A Prescribing amounts of active ingredients in dose of chemotherapy drug

In a chemotherapy prescription for a dose of any of the following chemotherapy drugs, the amounts of each active ingredient directed to be supplied must be in the same proportion as the proportion of the active ingredients in the form of a chemotherapy pharmaceutical benefit that has that chemotherapy drug:

(a) daunorubicin with cytarabine;

(b) nivolumab with relatlimab.

15 Maximum quantity (number of units)—related pharmaceutical benefits

(1) For the purposes of paragraph 85A(2)(a) of the Act, this section determines the maximum number of units of the pharmaceutical item in a related pharmaceutical benefit that an authorised prescriber may, in one prescription for a special arrangement supply of the benefit, direct to be supplied on any one occasion.

(2) If only one number of units is mentioned in the column of the table in Schedule 2 headed "Maximum Quantity" in relation to brands of the pharmaceutical item, that number of units is the maximum number of units of the pharmaceutical item for all purposes.

(3) If more than one number of units is mentioned in the column of the table in Schedule 2 headed "Maximum Quantity" in relation to brands of the pharmaceutical item, then:

(a) if a purposes code is mentioned in the column of the table headed "Purposes" in relation to a number of units—that number is the maximum number of units of the pharmaceutical item for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code; and

(b) if no purposes code is mentioned in the column in relation to a number of units—that number is the maximum number of units of the pharmaceutical item for all purposes other than purposes to which paragraph (a) applies.

Application of this section

(4) 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.

(5) 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.

16 Maximum number of repeats—chemotherapy drugs

(1) This section determines the maximum number of occasions an authorised prescriber may, in one chemotherapy prescription, direct that a special arrangement supply of a dose of a chemotherapy drug be repeated.

(2) If only one number is mentioned in the column of the table in Part 2 of Schedule 1 headed "Number of Repeats" in relation to the chemotherapy drug, that number is the maximum number of occasions for all purposes.

(3) If more than one number is mentioned in the column of the table in Part 2 of Schedule 1 headed "Number of Repeats" in relation to the chemotherapy drug, then:

(a) if a purposes code is mentioned in the column of the table headed "Purposes" in relation to a number—that number is the maximum number of occasions for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code; and

(b) if no purposes code is mentioned in the column in relation to a number—that number is the maximum number of occasions for all purposes other than purposes to which paragraph (a) applies.

17 Maximum number of repeats—related pharmaceutical benefits

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

(2) If only one number is mentioned in the column of the table in Schedule 2 headed "Number of Repeats" in relation to the related pharmaceutical benefit, that number is the maximum number of occasions for all purposes.

(3) If more than one number is mentioned in the column of the table in Schedule 2 headed "Number of Repeats" in relation to the related pharmaceutical benefit, then:

(a) if a purposes code is mentioned in the column of the table headed "Purposes" in relation to a number—that number is the maximum number of occasions for the purposes mentioned in the table in Part 1 of Schedule 3 for that purposes code; and

(b) if no purposes code is mentioned in the column in relation to a number—that number is the maximum number of occasions for all purposes other than purposes to which paragraph (a) applies.

Application of this section

(4) 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.

(5) 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.

18 Variation of maximum amount or quantity or maximum number of repeats

Modified application of section 30 of the Regulations for chemotherapy prescriptions

(1) Section 30 of the Regulations applies in relation to a chemotherapy prescription as if:

(a) a reference to a determination under paragraph 85A(2)(a) of the Act were a reference to a determination of the maximum amount of a chemotherapy drug by section 14 of this instrument; and

(b) a reference to a determination under paragraph 85A(2)(b) of the Act were a reference to a determination by section 16 of this instrument.

Rules for related pharmaceutical benefits

(2) For the purposes of subsection 85A(3A) of the Act, this section determines rules that must be applied when deciding whether to authorise a variation of the application of a determination of the maximum number of units or maximum number of repeats in relation to a prescription for a special arrangement supply of a related pharmaceutical benefit.

(3) If the column of the table in Schedule 2 headed “Variations” includes a variation code in relation to a maximum number of units, the rules mentioned in the column of the table in Part 2 of Schedule 3 headed “Variation Rules” in relation to the variation code must be applied when deciding whether to authorise a variation of that maximum (to the extent that those rules relate to the number of units).

(4) If the column of the table in Schedule 2 headed “Variations” includes a variation code in relation to a maximum number of repeats, the rules mentioned in the column of the table in Part 2 of Schedule 3 headed “Variation Rules” in relation to the variation code must be applied when deciding whether to authorise a variation of that maximum (to the extent that those rules relate to the number of repeats).

Note: Rules may relate to the maximum number of units, the maximum number of repeats or both.

Application of this section

(5) To the extent that this section provides for a matter not provided for in the Listing Instrument, this section applies in addition to the Listing Instrument.

(6) To the extent that this section makes a different provision for a matter provided for in the Listing Instrument, this section applies despite the Listing Instrument.

19 Writing chemotherapy prescriptions that are not medication chart prescriptions

(1) This section applies in relation to a chemotherapy prescription that is not a medication chart prescription.

(2) The prescription must include the following information:
  (a) the name of the chemotherapy drug directed to be supplied;
  (b) the dose of the drug directed to be supplied;
  (c) if supply of the dose of the drug is to be repeated—the number of times it is to be repeated.

(3) The following provisions of the Regulations do not apply in relation to the writing of the prescription:
  (a) paragraph 40(1)(d) and subsection 40(2A);
  (b) paragraph 40(1)(e);
  (c) paragraph 40(1)(j) and section 49;
  (d) paragraph 40(3)(a).

Note: If the prescription includes directions about particular pharmaceutical benefits to be supplied, an approved supplier is not required to follow the prescriber's directions—see subsection 23(8).

20 Writing medication chart prescriptions

Chart is not required to be in approved form

(1) A chart used to write a chemotherapy prescription or a prescription for a special arrangement supply of a related pharmaceutical benefit:
  (a) is not required to be in a form approved under paragraph 41(5)(a) of the Regulations or meet the information requirements approved under paragraph 41(5)(b) of the Regulations; and
  (b) is taken to be a medication chart for the purposes of the Regulations despite paragraphs 41(4)(a) and (b) of the Regulations.

No application to persons receiving treatment in or at residential care services

(2) Subparagraph 41(1)(a)(i) of the Regulations does not apply to a medication chart prescription that is:
  (a) a chemotherapy prescription; or
  (b) a prescription for a special arrangement supply of a related pharmaceutical benefit.

Modified application of section 41 of the Regulations—electronic medication chart prescriptions

(3) For an electronic medication chart prescription that is a chemotherapy prescription or a prescription for a special arrangement supply of a related pharmaceutical benefit:
  (a) paragraph 41(2)(c) of the Regulations does not apply; and
  (b) the authorised prescriber must approve the prescription in the electronic system used to write the prescription; and
  (c) paragraph 104(3)(b) of the Regulations does not apply.

Modifications for chemotherapy drugs only

(4) A medication chart prescription that is a chemotherapy prescription must include the following information:
  (a) the name of the chemotherapy drug directed to be supplied;
  (b) the dose of the chemotherapy drug directed to be supplied;
  (c) the frequency of administration and route of administration of the dose;
  (d) the date of the prescription.

(5) The following provisions of the Regulations do not apply in relation to the writing of a medication chart prescription that is a chemotherapy prescription:
  (a) subparagraph 41(2)(a)(i) and subsection 41(2A);
  (b) subparagraph 41(2)(a)(ii);
  (c) subparagraph 41(2)(a)(iii).

Note: If the prescription does include directions about particular pharmaceutical benefits to be supplied, an approved supplier is not required to follow the prescriber's directions—see subsection 23(8).

21 Direction to vary prescribed dose of chemotherapy drug

(1) An authorised prescriber who has written a chemotherapy prescription for a dose of a chemotherapy drug may direct an approved supplier that is to supply the dose on the basis of the prescription to increase or decrease the dose to be supplied, without writing a new prescription, if the new dose is between 90% and 110% of the dose that was originally prescribed.

(1A) If the direction is for a new dose of a chemotherapy drug mentioned in section 14A, the amounts of each active ingredient in the new dose must be in the same proportion as the proportion of the active ingredients in the form of a chemotherapy pharmaceutical benefit that has that chemotherapy drug.

(2) A new dose directed in accordance with subsections (1) and (1A) that is greater than the maximum amount for the chemotherapy drug determined by section 14 of this instrument does not require approval under section 30 of the Regulations as modified by subsection 18(1) of this instrument.

(3) If an approved supplier receives a direction in accordance with subsections (1) and (1A), the supplier must record on the chemotherapy prescription:

(a) the new dose of the chemotherapy drug as directed;
(b) the name of the authorised prescriber who gave the direction; and
(c) the means by which the supplier received the direction (for example, by phone or by fax); and
(d) the date and time the supplier received the direction.

(4) If an approved supplier records the information mentioned in subsection (3) on a chemotherapy prescription, the prescription is taken to be varied accordingly.

Division 3—Supplying doses of chemotherapy drugs and related pharmaceutical benefits

22 Entitlement to receive special arrangement supplies

(1) A person is entitled to receive a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit without payment or other consideration, other than a charge made under Part 4, if the person is an eligible patient for the chemotherapy drug or related pharmaceutical benefit.

(2) A person is not entitled to receive a special arrangement supply of a dose of a chemotherapy drug unless it is supplied by an approved supplier on presentation of a chemotherapy prescription written in accordance with Division 2.

(3) This section has effect in addition to sections 86 and 89 of the Act.

23 Special arrangement supplies of doses of chemotherapy drugs

(1) Subject to this section, an approved supplier may make a special arrangement supply of a dose of a chemotherapy drug on presentation of a chemotherapy prescription for the dose.

(2) The supply of the dose must be made from chemotherapy pharmaceutical benefits.

Rules for approved pharmacists modified

(3) Despite sections 89 and 90 of the Act, an approved pharmacist may make the supply of the dose other than at or from the premises in respect of which the pharmacist is for the time being approved.

(4) The *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017*, other than sections 6 and 7, does not apply to the supply of the dose.

Method of administration and circumstances must be complied with

(5) If the prescription directs the dose of the chemotherapy drug to be administered by a particular method, the supply of the dose must be able to be administered by that method.

(6) Subsection (5) applies regardless of whether the method directed by the prescription is also a manner of administration for a chemotherapy pharmaceutical benefit that has the chemotherapy drug.

(7) If the prescription was authorised in circumstances mentioned in Part 1 of Schedule 3 in relation to the chemotherapy drug, the supply of the dose must be made only from chemotherapy pharmaceutical benefits for which the

circumstances code for those circumstances is mentioned in the column in Part 1 of Schedule 1 headed "Circumstances".

Directions as to form, brand, quantity of benefits and number of repeats of benefits may be disregarded

(8) The approved supplier may disregard any directions as to the following that are included in the prescription:
  (a) the supply of a form of the chemotherapy drug;
  (b) the supply of a listed brand of a pharmaceutical item;
  (c) the supply of a quantity or number of units of a particular chemotherapy pharmaceutical benefit;
  (d) the number of times the supply of a particular chemotherapy pharmaceutical benefit is to be repeated.

Note: The matters in subsection (8) are not required to be included in chemotherapy prescriptions (see sections 19 and 20).

24 Rules not applicable to special arrangement supplies of chemotherapy drugs

Early supply of pharmaceutical benefit not applicable

(1) A special arrangement supply of a dose of a chemotherapy drug is not an early supply of a specified pharmaceutical benefit within the meaning of subsection 84AAA(1) of the Act.

Restrictions on frequency of repeated supplies not applicable

(2) Subsections 51(2) to (4) of the Regulations do not apply to a special arrangement supply of a dose of a chemotherapy drug.

Note: The effect of those subsections is to restrict how soon a repeat supply may be made. There is no restriction on how soon a repeat supply of a chemotherapy drug may be made under this instrument.

Deferred supply authorisations not applicable

(3) Section 53 of the Regulations does not apply in relation to a special arrangement supply of a dose of a chemotherapy drug.

25 Modified rules for special arrangement supplies on the basis of an electronic medication chart prescription

For a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit on the basis of an electronic medication chart prescription:
  (a) paragraph 45(2)(c) of the Regulations does not apply; and
  (b) the supplier must verify the supply and the date of supply in the electronic system used to write the prescription; and

(c) section 61 of the Regulations applies as if the reference to the details referred to in paragraph 45(2)(c) of the Regulations includes a reference to the verification required by paragraph (b) of this section.

Part 3—Claims, information and payment

Division 1—Claims for payment and giving information

26 Modified requirements for claims or giving information

Under co-payment data

(1) A reference in the rules made by the Minister under subsections 98AC(4) and 99AAA(8) of the Act to under co-payment data is taken to include a reference to information relating to the special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit where the amount payable to the supplier under Division 2 of this Part is nil.

Supplies of doses of chemotherapy drugs

(2) For a claim or giving of information in relation to a special arrangement supply of a dose of a chemotherapy drug, the requirements in the rules made by the Minister under subsections 98AC(4) and 99AAA(8) of the Act are modified as follows:

(a) a reference to a pharmaceutical benefit includes a reference to a dose of a chemotherapy drug;

(b) a reference to an authority prescription in the rules includes a reference to an authority prescription within the meaning of this instrument;

(c) the claim or information must include the following:

(i) an identifying code for the chemotherapy drug;

(ii) the dose of the drug supplied;

(iii) the compounder ID of the site at which the compounder compounded the dose of the drug;

(iv) if the claim is made using the manual system referred to in section 99AAA of the Act, the eligible patient is a CTG registered patient and the supplier is a CTG supplier—an indicator that the eligible patient is a CTG registered patient;

(d) the supplier is not required to include the following in the claim or information:

(i) the PBS/RPBS Item Code for the supplied pharmaceutical benefit;

(ii) the brand of the supplied pharmaceutical item;

(iii) whether or not section 49 of the Regulations applies;

(iv) whether or not immediate supply was necessary.

Note: A special arrangement supply of a dose of a chemotherapy drug is taken to be a supply of a pharmaceutical benefit (see subsection 9(2) of this instrument).

Supplies of related pharmaceutical benefits—CTG registered patients and suppliers

(3) For a claim in relation to a special arrangement supply of a related pharmaceutical benefit, the requirements in the rules made by the Minister under subsections 98AC(4) and 99AAA(8) of the Act are modified as set out in subsection (4) of this section.

(4) If:

(a) a claim is made using the manual system referred to in section 99AAA of the Act; and

(b) the supplier is a CTG supplier; and

(c) the eligible patient is a CTG registered patient;

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

Division 2—Payment of claims

27 Payment of approved pharmacists and approved medical practitioners for supplies of doses of chemotherapy drugs

(1) Subject to section 40 of this instrument, an approved pharmacist or approved medical practitioner who makes a special arrangement supply of a dose of a chemotherapy drug to a patient 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 supply, entitled to be paid by the Commonwealth:

(a) for an original supply—the amount, if any, by which the dispensed price for the dose exceeds the amount that the approved pharmacist or approved medical practitioner was required to charge the patient under subsection 36(2) of this instrument for the supply; and

(b) for a repeated supply—the dispensed price for the dose.

Note: Section 40 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

(2) Subsection (1) applies despite subsections 99(2) and (2AA) of the Act.

(3) Paragraph 99(3)(b) of the Act does not apply to a special arrangement supply of a dose of a chemotherapy drug by an approved pharmacist.

28 Payment of approved hospital authorities for supplies

Purpose of section

(1) Subject to Part 5 of this instrument, this section determines, for the purposes of subsection 99(4) of the Act, the amount payable to an approved hospital authority in respect of a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit.

Note 1: Part 5 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug, and to a special arrangement supply of a related pharmaceutical benefit, if the supply is made to a CTG registered patient by a CTG supplier.

Note 2: Under this instrument, subsection 99(4) of the Act applies as if it includes a reference to patients receiving treatment from a hospital (see section 8 of this instrument).

(2) This section applies despite the *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017* (PB 25 of 2017) and the *National Health (Commonwealth Price - Pharmaceutical benefits supplied by private hospitals) Determination 2020* (PB 99 of 2020).

Supplies of doses of chemotherapy drugs

(3) The amount payable to an approved hospital authority in respect of a special arrangement supply of a dose of a chemotherapy drug to a patient is:

(a) for an original supply—the amount, if any, by which the dispensed price for the dose exceeds the amount that the hospital authority was entitled to

charge the patient under subsection 37(2) of this instrument for the supply; and

(b) for a repeat supply—the dispensed price for the dose.

Supplies of related pharmaceutical benefit

(4) The amount payable to a participating hospital authority in respect of a special arrangement supply of a related pharmaceutical benefit to a patient is the amount, if any, by which the dispensed price for the pharmaceutical benefit exceeds the amount the patient could have been required to pay in accordance with subsection 87(2) of the Act if the patient had obtained the related pharmaceutical benefit from an approved pharmacist.

Note: The participating hospital authority may charge the patient the amount mentioned in subsection 87(2) of the Act (see subsection 87(5) of the Act).

29 No separate entitlement to payment for supplies of diluent

(1) If an approved supplier adds a pharmaceutical benefit to the supply of a dose of a chemotherapy drug as a diluent, then despite section 99 of the Act no amount is payable for supply of the pharmaceutical benefit.

(2) Subsection (1) applies regardless of whether the pharmaceutical benefit added as a diluent is a related pharmaceutical benefit.

30 Payment of TGA-licensed compounders

If a TGA-licensed compounder compounds a dose of a chemotherapy drug for a special arrangement supply of the dose, the compounder is entitled to be paid a TGA-licensed compounding fee by the Commonwealth for compounding the dose.

Note: Information about the compounder is included in the claim by the supplier of the chemotherapy drug or in information about the supply: see subsection 26(2).

Division 3—Dispensed price for dose of chemotherapy drug

31 Dispensed price for doses supplied by approved pharmacists and approved medical practitioners

(1) For a dose of a chemotherapy drug supplied by an approved pharmacist or an approved medical practitioner, the ***dispensed price*** is the sum of the following amounts:

(a) the base price for the dose worked out under subsection (2);
(b) the distribution fee;
(c) the dispensing fee;
(d) the preparation fee;
(e) the diluent fee.

(2) The base price for a dose of a chemotherapy drug is the lowest sum of reference prices for a chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that make up an amount of the drug equal to or greater than the dose.

Note: If there is more than one chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that contains enough of the drug to make up the dose, the base price is determined by the lowest priced benefit or combination of benefits.

(3) A combination of chemotherapy pharmaceutical benefits includes a quantity of 2 or more of the same chemotherapy pharmaceutical benefit.

Example: Two of the same chemotherapy pharmaceutical benefit, each of which contains 50 mg of a drug, could be used in combination to make up an amount of 100 mg of the drug. The reference price for each 50 mg would be added together to calculate the price of the combination.

(4) In this section, the ***reference price*** of a chemotherapy pharmaceutical benefit is the sum, rounded to the nearest cent (with a half cent being rounded up), of:

(a) the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit, rounded to the nearest cent (with a half cent being rounded up); and
(b) the mark-up for the chemotherapy pharmaceutical benefit worked out under section 32.

32 Mark-up for a chemotherapy pharmaceutical benefit

(1) For the purposes of paragraph 31(4)(b), the mark-up for a chemotherapy pharmaceutical benefit is:

$$\frac{\text{mark-up for maximum units}}{\text{maximum units of pharmaceutical benefit}}$$

where:

mark-up for maximum units means the amount worked out:

(a) if the chemotherapy pharmaceutical benefit does not have trastuzumab—under subsection (2); or

(b) if the chemotherapy pharmaceutical benefit has trastuzumab—under subsection (3).

maximum units of pharmaceutical benefit is the whole number of units of the chemotherapy pharmaceutical benefit required to obtain the maximum amount of the chemotherapy drug in the benefit that is determined by section 14.

(2) The following table sets out how to work out the mark-up for maximum units for a chemotherapy pharmaceutical benefit that does not have trastuzumab.

Mark-up for pharmaceutical benefit that does not have trastuzumab

Item	Column 1 If the maximum units ex-manufacturer price for the pharmaceutical benefit is …	Column 2 the mark-up for maximum units is …
1	less than $100	$4.62
2	at least $100 but not more than $2,000	$4.62 plus 5% of the amount by which the maximum units ex-manufacturer price exceeds $100
3	more than $2,000	$99.62

(3) The following table sets out how to work out the mark-up for maximum units for a chemotherapy pharmaceutical benefit that has trastuzumab.

Mark-up for pharmaceutical benefit that has trastuzumab

Item	Column 1 If the maximum units ex-manufacturer price for the pharmaceutical benefit is …	Column 2 the mark-up for maximum units is …
1	not more than $40	10% of the maximum units ex-manufacturer price
2	more than $40 but not more than $100	$4
3	more than $100 but not more than $1,000	4% of the maximum units ex-manufacturer price
4	more than $1,000	$40

(4) For the purposes of subsections (2) and (3), the ***maximum units ex-manufacturer price*** of a chemotherapy pharmaceutical benefit that is a listed brand of a pharmaceutical item is:

$$\frac{\text{AEMP}}{\text{pricing quantity}} \times \text{maximum units of pharmaceutical benefit}$$

where:

AEMP means the approved ex-manufacturer price of the chemotherapy pharmaceutical benefit.

maximum units of pharmaceutical benefit has the meaning given by subsection (1).

pricing quantity means the pricing quantity of the chemotherapy pharmaceutical benefit.

33 Dispensed price if dose is supplied by approved private hospital authority

(1) For a dose of a chemotherapy drug supplied by an approved hospital authority of a private hospital, the ***dispensed price*** is the sum of the following amounts:
  (a) the base price for the dose worked out under subsection (2);
  (b) for a drug other than trastuzumab—the distribution fee;
  (c) the dispensing fee;
  (d) the preparation fee;
  (e) the diluent fee.

(2) The base price for a dose of a chemotherapy drug is the lowest sum of reference prices for a chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that make up an amount of the drug equal to or greater than the dose.

Note: If there is more than one chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that contains enough of the drug to make up the dose, the base price is determined by the lowest priced benefit or combination of benefits.

(3) A combination of chemotherapy pharmaceutical benefits includes a quantity of 2 or more of the same chemotherapy pharmaceutical benefit.

Example: Two of the same chemotherapy pharmaceutical benefit, each of which contains 50 mg of a drug, could be used in combination to make up an amount of 100 mg of the drug. The reference price for each 50 mg would be added together to calculate the price of the combination.

(4) In this section, the ***reference price*** of a chemotherapy pharmaceutical benefit is the sum, rounded to the nearest cent (with a half cent being rounded up), of:
  (a) the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit, rounded to the nearest cent (with a half cent being rounded up); and
  (b) 1.4% of the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit.

34 Dispensed price if dose is supplied by approved public hospital authority

(1) For a dose of a chemotherapy drug supplied by an approved hospital authority of a public hospital, the ***dispensed price*** is the sum of the following amounts:
  (a) the base price for the dose worked out under subsection (2);
  (b) the preparation fee.

(2) The base price for a dose of a chemotherapy drug is the lowest sum of reference prices for a chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that make up an amount of the drug equal to or greater than the dose.

Note: If there is more than one chemotherapy pharmaceutical benefit or combination of chemotherapy pharmaceutical benefits that contains enough of the drug to make up the dose, the base price is determined by the lowest priced benefit or combination of benefits.

(3) A combination of chemotherapy pharmaceutical benefits includes a quantity of 2 or more of the same chemotherapy pharmaceutical benefit.

Example: Two of the same chemotherapy pharmaceutical benefit, each of which contains 50 mg of a drug, could be used in combination to make up an amount of 100 mg of the drug. The reference price for each 50 mg would be added together to calculate the price of the combination.

(4) In this section, the ***reference price*** of a chemotherapy pharmaceutical benefit is the single unit ex-manufacturer price for the chemotherapy pharmaceutical benefit, rounded to the nearest cent (with a half cent being rounded up).

Division 4—Dispensed price for related pharmaceutical benefit

35 Dispensed price for supply of related pharmaceutical benefit

(1) The ***dispensed price*** for a special arrangement supply of a related pharmaceutical benefit that is a listed brand of a pharmaceutical item is as follows:

(a) if the quantity of the benefit supplied is equal to a multiple of a pack quantity of the benefit—the sum of the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for each pack quantity;

(b) if the quantity of the benefit supplied is less than a pack quantity of the benefit (a ***broken quantity***)—the amount worked out in accordance with subsection (2);

(c) if neither paragraph (a) or (b) applies to the quantity of the benefit supplied—the sum of:

(i) the approved ex-manufacturer price or the proportional ex-manufacturer price (as applicable) for each pack quantity; and

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

(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.

(3) The dispensed price under subsection (1) is rounded to the nearest cent (with a half cent being rounded up).

Part 4—Patient contributions

36 Supplies of doses of chemotherapy drugs by approved pharmacists and approved medical practitioners

(1) Subject to section 40 of this instrument, this section sets out amounts that an approved pharmacist or approved medical practitioner must or may charge an eligible patient for a special arrangement supply of a dose of a chemotherapy drug.

Note: Section 40 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

Patient co-payment must be charged for original supply only

(2) For an original supply of a dose, the approved pharmacist or approved medical practitioner must charge the patient an amount that is equivalent to the amount that may be charged under subsection 87(2) of the Act for the supply of a pharmaceutical benefit to the patient.

Note: This is a single amount for supply of the dose, not a separate amount for supply of each chemotherapy pharmaceutical benefit used to make the dose.

(3) No amount may be charged under subsection (2) for a repeated supply.

(3A) In addition, if the supply is made to an eligible patient who is a CTG registered patient by a CTG supplier, no amount may be charged under subsections 11(1) to (3) of the CTG Special Arrangement for a repeated supply.

Note: See section 40 of this instrument in relation to the application of the CTG Special Arrangement.

Special patient contribution for original or repeated supply

(4) If a determination under subsection 85B(3) of the Act is in force in relation to a chemotherapy pharmaceutical benefit used to make the dose:

(a) the approved pharmacist or approved medical practitioner may charge a special patient contribution in accordance with the Act for supply of the benefit; and

(b) subsection 85B(5) of the Act applies as if a reference to the Commonwealth price for a quantity or number of units of a listed brand of a pharmaceutical item were a reference to the dispensed price for a dose of a chemotherapy drug made using a quantity or number of units of a listed brand of a pharmaceutical item.

37 Supplies of doses of chemotherapy drugs by approved hospital authorities

(1) Subject to section 40 of this instrument, this section sets out amounts that an approved hospital authority may charge an eligible patient for a special arrangement supply of a dose of a chemotherapy drug.

Note: Section 40 of this instrument applies to an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

Patient co-payment may be charged for original supply only

(2) For an original supply of a dose, the hospital authority may charge the patient an amount not exceeding the amount that the patient could have been required to pay under subsection 87(2) of the Act if the patient had obtained a pharmaceutical benefit from an approved pharmacist.

Note: This is a single amount for supply of the dose, not a separate amount for supply of each chemotherapy pharmaceutical benefit used to make the dose.

(3) No amount may be charged under subsection (2) for a repeated supply.

(3A) In addition, if the supply is made to an eligible patient who is a CTG registered patient by a CTG supplier, no amount may be charged under subsections 11(1) to (3) of the CTG Special Arrangement for a repeated supply.

Note: See section 40 of this instrument in relation to the application of the CTG Special Arrangement.

Special patient contribution for original or repeated supply

(4) If a determination under subsection 85B(3) of the Act is in force in relation to a chemotherapy pharmaceutical benefit used to make the dose:

(a) the hospital authority may charge a special patient contribution in accordance with the Act for supply of the benefit; and

(b) subsection 85B(5) of the Act applies as if a reference to the Commonwealth price for a quantity or number of units of a listed brand of a pharmaceutical item were a reference to the dispensed price for a dose of a chemotherapy drug made using a quantity or number of units of a listed brand of a pharmaceutical item.

38 Supplies of related pharmaceutical benefits—special patient contribution

If a determination under subsection 85B(3) of the Act is in force in relation to a related pharmaceutical benefit, subsection 85B(5) of the Act applies to a special arrangement supply of the related pharmaceutical benefit as if a reference to the Commonwealth price were a reference to the dispensed price.

39 Application of safety net provisions

(1) Subparagraph 84C(4)(a)(i) of the Act applies to a special arrangement supply of a dose of a chemotherapy drug or of a related pharmaceutical benefit as if the words “at or from premises in respect of which the pharmacist is for the time being approved” were omitted.

(2) The ***value for safety net purposes*** for an original special arrangement supply of a dose of a chemotherapy drug to a person is the amount paid by the person for the supply of the dose under subsection 36(2) or 37(2).

Note 1: However, see section 40 of this instrument for an original special arrangement supply of a dose of a chemotherapy drug if the supply is made to a CTG registered patient by a CTG supplier.

Note 2: A special arrangement supply of a dose of a chemotherapy drug is taken to be a supply of a pharmaceutical benefit (see subsection 9(2) of this instrument).

(3) The ***value for safety net purposes*** for a repeated special arrangement supply of a dose of a chemotherapy drug to a person is zero.

Note: A person must not be charged a patient co-payment for a repeat supply but may be charged a special patient contribution if applicable (see sections 36 and 37).

(4) This section applies despite section 17A of the Regulations.

Part 5—Supply to CTG registered patients by CTG suppliers

40 Application of the CTG Special Arrangement—original special arrangement supply of a dose of a chemotherapy drug

(1) This section applies to an original special arrangement supply (the ***relevant supply***) of a dose of a chemotherapy drug under this instrument if the relevant supply is made:

(a) to an eligible patient who is a CTG registered patient; and

(b) by an approved pharmacist, an approved medical practitioner or an approved hospital authority who is a CTG supplier.

(2) Despite paragraphs 27(1)(a) and 28(3)(a) and subsections 36(2), 37(2) and 39(2) of this instrument, subsections 11(1), (2), (3) and (4) (co-payment reduction etc.) and section 13 (payment by Commonwealth) of the CTG Special Arrangement apply in relation to the relevant supply under this instrument with the modification set out in subsection (3) of this section.

(3) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this instrument.

(4) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this instrument.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this instrument are instead dealt with under section 26 of this instrument.

41 Application of the CTG Special Arrangement—special arrangement supply of a related pharmaceutical benefit

(1) This section applies to a special arrangement supply (the ***relevant supply***) of a related pharmaceutical benefit under this instrument if the relevant supply is made:

(a) to an eligible patient who is a CTG registered patient; and

(b) by a participating hospital authority who is a CTG supplier.

(2) Subsections 11(1), (2), (3) and (4) (co-payment reduction etc.) of the CTG Special Arrangement apply in relation to the relevant supply under this instrument with the modification set out in subsection (5) of this section.

(3) Subsection (2) applies despite subsection 87(5) of the Act.

(4) In addition, despite subsection 28(4) of this instrument, section 13 (payment by Commonwealth) of the CTG Special Arrangement applies in relation to the

relevant supply under this instrument with the modification set out in subsection (5) of this section.

(5) A reference in the CTG Special Arrangement to a supply of a pharmaceutical benefit under the CTG Special Arrangement is taken to be a reference to the relevant supply under this instrument.

(6) However, the notes to subsections 11(2) and (3) of the CTG Special Arrangement do not apply in relation to the relevant supply under this instrument.

Note: The notes to subsections 11(2) and (3) of the CTG Special Arrangement relate to CTG suppliers making claims for payment under the CTG Special Arrangement. Claims for payment in relation to the relevant supply under this instrument are instead dealt with under section 26 of this instrument.

Schedule 1—Chemotherapy pharmaceutical benefits and chemotherapy drugs

Note: See the definitions of ***chemotherapy drug*** and ***chemotherapy pharmaceutical benefit*** in section 5, and sections 12, 14, 16 and 23.

Part 1—Chemotherapy pharmaceutical benefits

1 Chemotherapy pharmaceutical drugs and chemotherapy pharmaceutical benefits

(1) Each listed drug specified in the following table is a chemotherapy drug.

(2) Each pharmaceutical benefit specified in the following table is a chemotherapy pharmaceutical benefit.

(3) The following table also specifies circumstances for chemotherapy 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 administrations and brands mentioned in the table have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

Listed Drug	Form	Manner of Administration	Brand	Circumstances
Arsenic	Injection concentrate containing arsenic trioxide 10 mg in 10 mL	Injection	Arsenic Trioxide Accord	C4793 C5997 C6018
			Arsenic Trioxide Juno	C4793 C5997 C6018
			Arsenic Trioxide-AFT	C4793 C5997 C6018
			Phenasen	C4793 C5997 C6018
Atezolizumab	Solution concentrate for I.V. infusion 840 mg in 14 mL	Injection	Tecentriq	C10215 C10257 C10509 C10972 C13446 C13451
	Solution concentrate for I.V. infusion 1200 mg in 20 mL	Injection	Tecentriq	C10125 C10206 C10216 C10297 C10521 C10917

Listed Drug	Form	Manner of Administration	Brand	Circumstances
				C10939 C13442 C13443 C13448
Avelumab	Solution concentrate for I.V. infusion 200 mg in 10 mL	Injection	Bavencio	C13290 C15485 C16053 C16085
Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg	Injection	Bendamustine Juno	C7943 C7944 C7972
			Bendamustine Sandoz	C7943 C7944 C7972
			Bendamustine Viatris	C7943 C7944 C7972
	Powder for injection containing bendamustine hydrochloride 100 mg	Injection	Bendamustine Juno	C7943 C7944 C7972
			Bendamustine Sandoz	C7943 C7944 C7972
			Bendamustine Viatris	C7943 C7944 C7972
Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL	Injection	Abevmy	
			Bevaciptin	
			Mvasi	
			Vegzelma	
	Solution for I.V. infusion 400 mg in 16 mL	Injection	Abevmy	
			Bevaciptin	
			Mvasi	
			Vegzelma	
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	DBL Bleomycin Sulfate	C6224 C6275
Blinatumomab	Powder for I.V. infusion 38.5 micrograms	Injection	Blincyto	C9369 C9519 C14587 C14588 C14631
Bortezomib	Powder for injection 1 mg	Injection	Bortezomib Accord	C11099 C13745
			DBL Bortezomib	C11099 C13745
	Powder for injection 2.5 mg	Injection	Bortezomib Juno	C11099 C13745

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances
			DBL Bortezomib	C11099 C13745
	Powder for injection 3 mg	Injection	DBL Bortezomib	C11099 C13745
	Powder for injection 3.5 mg	Injection	Bortezom	C11099 C13745
			Bortezomib Accord	C11099 C13745
			Bortezomib Baxter	C11099 C13745
			BORTEZOMIB EUGIA	C11099 C13745
			Bortezomib Juno	C11099 C13745
			Bortezomib Sandoz	C11099 C13745
			DBL Bortezomib	C11099 C13745
	Solution for injection 2.5 mg in 1 mL	Injection	Bortezomib Accord	C11099 C13745
			Bortezomib Ever Pharma	C11099 C13745
	Solution for injection 3.5 mg in 1.4 mL	Injection	Bortezomib Accord	C11099 C13745
			Bortezomib Ever Pharma	C11099 C13745
Brentuximab vedotin	Powder for I.V. infusion 50 mg	Injection	Adcetris	C13134 C13179 C13181 C13182 C13208 C13209 C13212 C13231 C13259 C13261
Cabazitaxel	Concentrated injection 60 mg in 1.5 mL, with diluent	Injection	Cabazitaxel Juno	C13207
			MSN Cabazitaxel	C13207
	Solution concentrate for I.V. infusion 60 mg in 3 mL	Injection	Cabazitaxel Accord	C13207
	Solution concentrate for I.V. infusion 60 mg in 6 mL	Injection	Cabazitaxel Ever Pharma	C13207
Carboplatin	Solution for I.V. injection 450 mg in 45 mL	Injection	Carboplatin Accord	
Carfilzomib	Powder for injection 10 mg	Injection	Kyprolis	C12694 C12849

Listed Drug	Form	Manner of Administration	Brand	Circumstances
				C12930 C12934 C14363 C14364 C14389
	Powder for injection 30 mg	Injection	Kyprolis	C12694 C12849 C12930 C12934 C14363 C14364 C14389
	Powder for injection 60 mg	Injection	Kyprolis	C12694 C12849 C12930 C12934 C14363 C14364 C14389
Cemiplimab	Solution concentrate for I.V. infusion 350 mg in 7 mL	Injection	Libtayo	C13411 C13419 C15063 C15094
Cetuximab	Solution for I.V. infusion 100 mg in 20 mL	Injection	Erbitux	C4785 C4788 C4794 C4908 C4912 C12016 C12045 C12470 C12483
	Solution for I.V. infusion 500 mg in 100 mL	Injection	Erbitux	C4785 C4788 C4794 C4908 C4912 C12016 C12045 C12470 C12483
Cisplatin	I.V. injection 50 mg in 50 mL	Injection	Cisplatin Accord	
	I.V. injection 100 mg in 100 mL	Injection	Cisplatin Accord	
Cladribine	Injection 10 mg in 5 mL	Injection	Litak	C6265
	Solution for I.V. infusion 10 mg in 10 mL single use vial	Injection	Leustatin	C6265
Cyclophosphamide	Powder for injection 500 mg (anhydrous)	Injection	CYCLOPHOSPHAMIDE-REACH	
	Powder for injection 1 g (anhydrous)	Injection	CYCLOPHOSPHAMIDE-REACH	

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances
			Endoxan	
	Powder for injection 2 g (anhydrous)	Injection	Endoxan	
Cytarabine	Injection 100 mg in 5 mL vial	Injection	Pfizer Australia Pty Ltd	
Daratumumab	Solution concentrate for I.V. infusion 100 mg in 5 mL	Injection	Darzalex	C12691 C12845 C13752
	Solution concentrate for I.V. infusion 400 mg in 20 mL	Injection	Darzalex	C12691 C12845 C13752
Daunorubicin with cytarabine	Powder for I.V. infusion containing daunorubicin 44 mg (as hydrochloride) and cytarabine 100 mg	Injection	Vyxeos	C16187 C16197
Docetaxel	Solution concentrate for I.V. infusion 80 mg in 4 mL	Injection	Docetaxel Accord	
	Solution concentrate for I.V. infusion 80 mg in 8 mL	Injection	DBL Docetaxel Concentrated Injection	
	Solution concentrate for I.V. infusion 160 mg in 8 mL	Injection	Docetaxel Accord	
	Solution concentrate for I.V. infusion 160 mg in 16 mL	Injection	DBL Docetaxel Concentrated Injection	
Dostarlimab	Solution concentrate for I.V. infusion 500 mg in 10 mL	Injection	Jemperli	C15163 C15196 C15205
Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 50 mg in 25 mL single dose vial	Injection/intravesical	Adriamycin	
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial	Injection/intravesical	Adriamycin	
			Doxorubicin ACC	
Doxorubicin - pegylated liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	
			Liposomal Doxorubicin SUN	
	Suspension for I.V. infusion containing pegylated liposomal doxorubicin	Injection	Caelyx	

Listed Drug	Form	Manner of Administration	Brand	Circumstances
	hydrochloride 50 mg in 25 mL			
			Liposomal Doxorubicin SUN	
Durvalumab	Solution concentrate for I.V. infusion 120 mg in 2.4 mL	Injection	Imfinzi	C10206 C10509 C12271 C14708 C15500
	Solution concentrate for I.V. infusion 500 mg in 10 mL	Injection	Imfinzi	C10206 C10509 C12271 C14708 C15500
Elotuzumab	Powder for injection 300 mg	Injection	Empliciti	C12847
	Powder for injection 400 mg	Injection	Empliciti	C12847
Enfortumab vedotin	Powder for I.V. infusion 20 mg	Injection	Padcev	C14416
	Powder for I.V. infusion 30 mg	Injection	Padcev	C14416
Epirubicin	Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL	Injection/intravesical	Epirubicin Accord	
Eribulin	Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL	Injection	Halaven	C4649 C7258 C7280
Etoposide	Powder for I.V. infusion 1 g (as phosphate)	Injection	Etopophos	
	Solution for I.V. infusion 100 mg in 5 mL	Injection	Etoposide Ebewe	
Fludarabine	Powder for I.V. injection containing fludarabine phosphate 50 mg	Injection	Fludarabine Juno	
	Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL	Injection	Fludarabine Ebewe	
Fluorouracil	Injection 500 mg in 10 mL	Injection	Fluorouracil Accord	C6266 C6297
	Injection 1000 mg in 20 mL	Injection	Fluorouracil Accord	C6266 C6297
			Fluorouracil Ebewe	C6266 C6297
	Injection 2500 mg in 50 mL	Injection	Fluorouracil Accord	C6266 C6297
	Injection 5000 mg in 100 mL	Injection	Fluorouracil Accord	C6266 C6297

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances
			Fluorouracil Ebewe	C6266 C6297
Gemcitabine	Solution for injection 1 g (as hydrochloride) in 26.3 mL	Injection	DBL Gemcitabine Injection	
	Solution for injection 2 g (as hydrochloride) in 52.6 mL	Injection	DBL Gemcitabine Injection	
Gemtuzumab ozogamicin	Powder for injection 5 mg	Injection	Mylotarg	C12559 C12566
Idarubicin	Solution for I.V. injection containing idarubicin hydrochloride 5 mg in 5 mL	Injection	Zavedos Solution	C6247
Ifosfamide	Powder for I.V. injection 1 g	Injection	Holoxan	
	Powder for I.V. injection 2 g	Injection	Holoxan	
Inotuzumab ozogamicin	Powder for I.V. infusion 1 mg	Injection	Besponsa	C9470 C9601
Ipilimumab	Injection concentrate for I.V. infusion 50 mg in 10 mL	Injection	Yervoy	C6562 C6585 C8555 C11391 C11478 C11930 C14808
	Injection concentrate for I.V. infusion 200 mg in 40 mL	Injection	Yervoy	C6562 C6585 C14808
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL	Injection	Omegapharm Irinotecan	
	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Irinotecan Accord	
			Irinotecan Alphapharm	
			IRINOTECAN BAXTER	
			Omegapharm Irinotecan	
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Injection	Irinotecan Accord	
			Irinotecan Alphapharm	
Methotrexate	Injection 5 mg in 2 mL vial	Injection	DBL Methotrexate	

Listed Drug	Form	Manner of Administration	Brand	Circumstances
	Injection 50 mg in 2 mL vial	Injection	DBL Methotrexate	
	Solution concentrate for I.V. infusion 500 mg in 20 mL vial	Injection	DBL Methotrexate	
	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial	Injection	DBL Methotrexate	
			Methotrexate Accord	
	Solution concentrate for I.V. infusion 5000 mg in 50 mL vial	Injection	Methotrexate Ebewe	
Mitozantrone	Injection 20 mg (as hydrochloride) in 10 mL	Injection	Mitozantrone Ebewe	
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	C9216 C9252 C9298 C9299 C9312 C9321 C10119 C10120 C11468 C11477 C11985 C13433 C13445 C13839 C13900 C14001 C14676 C14816 C14830 C15471 C15527
	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	C9216 C9252 C9298 C9299 C9312 C9321 C10119 C10120 C11468 C11477 C11985 C13433 C13445 C13839 C13900 C14001 C14676 C14816 C14830 C15471 C15527
Nivolumab with relatlimab	Solution concentrate for I.V. infusion containing 240 mg nivolumab and 80 mg relatlimab in 20 mL	Injection	Opdualag	C16151 C16188
Obinutuzumab	Solution for I.V. infusion 1000 mg in 40 mL	Injection	Gazyva	C11015 C11755 C11785 C11787 C11815 C14326

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances
				C14764
Oxaliplatin	Solution concentrate for I.V. infusion 100 mg in 20 mL	Injection	Oxaliplatin Accord	
	Solution concentrate for I.V. infusion 200 mg in 40 mL	Injection	Oxaliplatin SUN	
Paclitaxel	Solution concentrate for I.V. infusion 300 mg in 50 mL	Injection	Paclitaxel Accord	
			Paclitaxel Ebewe	
Paclitaxel, nanoparticle albumin-bound	Powder for I.V. injection containing 100 mg paclitaxel	Injection	Abraxane	C4657 C6106 C6119
Panitumumab	Solution concentrate for I.V. infusion 100 mg in 5 mL	Injection	Vectibix	C5452 C5526 C12035 C12066
	Solution concentrate for I.V. infusion 400 mg in 20 mL	Injection	Vectibix	C5452 C5526 C12035 C12066
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	C10676 C10688 C10701 C10705 C13431 C13432 C13436 C13437 C13726 C13727 C13728 C13730 C13731 C13732 C13735 C13736 C13739 C13741 C13948 C13949 C14027 C14044 C14324 C14403 C14404 C14727 C14770 C14786 C14817 C14818
Pemetrexed	Powder for I.V. infusion 100 mg (as disodium)	Injection	Pemetrexed Accord	
			Pemetrexed SUN	
	Powder for I.V. infusion 500 mg (as disodium)	Injection	Pemetrexed Accord	

Listed Drug	Form	Manner of Administration	Brand	Circumstances
			Pemetrexed APOTEX	
			Pemetrexed SUN	
	Powder for I.V. infusion 1 g (as disodium)	Injection	Pemetrexed Accord	
			Pemetrexed SUN	
	Solution concentrate for I.V. infusion 100 mg (as disodium) in 4 mL	Injection	Pemetrexed Ever Pharma	
	Solution concentrate for I.V. infusion 500 mg (as disodium) in 20mL	Injection	Pemetrexed Ever Pharma	
	Solution concentrate for I.V. infusion 1 g (as disodium) in 40 mL	Injection	Pemetrexed Ever Pharma	
Pertuzumab	Solution for I.V. infusion 420 mg in 14 mL	Injection	Perjeta	C10414 C13018
Pralatrexate	Solution for I.V. infusion 20 mg in 1 mL	Injection	Folotyn	C7526 C7558
Raltitrexed	Powder for I.V. infusion 2 mg in single use vial	Injection	Tomudex	
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Ruxience	
			Riximyo	
			Truxima	
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Riximyo	
			Ruxience	
			Truxima	
Sacituzumab govitecan	Powder for injection 180 mg	Injection	Trodelvy	C12656 C12669
Tebentafusp	Solution concentrate for I.V. infusion 100 micrograms in 0.5 mL	Injection	Kimmtrak	C14813 C14821 C14825 C15085
Topotecan	Powder for I.V. infusion 4 mg (as hydrochloride)	Injection	Hycamtin	
	Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride)	Injection	Topotecan Accord	
Trabectedin	Powder for I.V. infusion 1 mg	Injection	Yondelis	C14196 C14197
Trastuzumab	Powder for I.V. infusion 60 mg	Injection	Trazimera	C9349 C9353 C9571

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances
				C9573 C10213 C10294 C15820 C15831
	Powder for I.V. infusion 150 mg	Injection	Herzuma	C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831
			Kanjinti	C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831
			Ogivri	C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831
			Trazimera	C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831
	Powder for I.V. infusion 420 mg	Injection	Kanjinti	C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831
	Powder for I.V. infusion 440 mg with diluent	Injection	Herzuma	C9349 C9353 C9571 C9573 C10213 C10294 C15820 C15831
Trastuzumab deruxtecan	Powder for I.V. infusion 100 mg	Injection	Enhertu	C15826 C15832
Trastuzumab emtansine	Powder for I.V. infusion 100 mg	Injection	Kadcyla	C15818 C15819 C15827 C15828

Listed Drug	Form	Manner of Administration	Brand	Circumstances
	Powder for I.V. infusion 160 mg	Injection	Kadcyla	C15818 C15819 C15827 C15828
Vinblastine	Solution for I.V. injection containing vinblastine sulfate 10 mg in 10 mL	Injection	DBL Vinblastine	
Vincristine	I.V. injection containing vincristine sulfate 1 mg in 1 mL	Injection	DBL Vincristine Sulfate	
Vinorelbine	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	Injection	Vinorelbine Ebewe	
	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	Injection	Navelbine	
			Vinorelbine Ebewe	

Part 2—Maximum amounts and number of repeats for chemotherapy drugs

2 Maximum amounts and number of repeats

For each chemotherapy drug, the following table specifies:

(a) the maximum amount of the drug that may be directed to be supplied on any one occasion; and

(b) the maximum number of occasions that, in one chemotherapy prescription, supply of a dose of the drug may be directed to be repeated.

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Arsenic	P4793 P5997	18 mg	89
	P6018	18 mg	140
Atezolizumab	P10206 P10939	1200 mg	3
	P10521	1200 mg	4
	P10125 P13443 P13448	1200 mg	5
	P10216 P10297 P13442	1200 mg	7
	P10917	1200 mg	8
	P10509 P13446	1680 mg	3
	P10215 P10257 P10972 P13451	1680 mg	5
Avelumab	P15485	800 mg	7
	P13290	800 mg	11
	P16053	1200 mg	8
	P16085	1200 mg	11
Bendamustine		200 mg	11
Bevacizumab		1800 mg	7
Bleomycin		30000 iu	11
Blinatumomab	P14588	651 mcg	0
	P9519	784 mcg	0
	P14587 P14631	784 mcg	1
	P9369	784 mcg	2
Bortezomib		3000 mcg	15
Brentuximab vedotin	P13179	180 mg	3
	P13181	180 mg	11

Listed Drug	Purposes	Maximum Amount	Number of Repeats
	P13212	200 mg	1
	P13182 P13209 P13259	200 mg	3
	P13134	200 mg	5
	P13208 P13231 P13261	200 mg	11
Cabazitaxel		55 mg	5
Carboplatin		900 mg	5
Carfilzomib	P14363 P14364 P14389	60 mg	17
	P12930 P12934	120 mg	17
	P12694 P12849	160 mg	8
Cemiplimab	P13419	350 mg	2
	P15063 P15094	350 mg	6
	P13411	350 mg	7
Cetuximab	P4788	550 mg	5
	P4785 P4794	880 mg	0
	P4908 P12045 P12483	1100 mg	0
	P12016 P12470	1100 mg	11
	P4912	1100 mg	18
Cisplatin		220 mg	14
Cladribine		17 mg	6
Cyclophosphamide		2800 mg	17
Cytarabine		7000 mg	15
Daratumumab	P12845	1920 mg	4
	P12691	1920 mg	5
	P13752	1920 mg	8
Daunorubicin with cytarabine	P16197	64 mg	3
	P16187	97 mg	4
Docetaxel		250 mg	5
Dostarlimab	P15163	500 mg	5
	P15196 P15205	1000 mg	3
Doxorubicin		135 mg	11
Doxorubicin - pegylated liposomal		100 mg	5
Durvalumab	P10206	1500 mg	3
	P12271 P15500	1500 mg	4

Clause 2

Listed Drug	Purposes	Maximum Amount	Number of Repeats
	P10509 P14708	1500 mg	5
Elotuzumab	P12847	1200 mg	5
Enfortumab vedotin		125 mg	8
Epirubicin		220 mg	5
Eribulin	P7258 P7280	3 mg	7
	P4649	3 mg	13
Etoposide		440 mg	14
Fludarabine		55 mg	29
Fluorouracil	P6297	1000 mg	23
	P6266	5500 mg	11
Gemcitabine		3000 mg	17
Gemtuzumab ozogamicin	P12566	5 mg	1
	P12559	5 mg	2
Idarubicin		30 mg	5
Ifosfamide		4000 mg	19
Inotuzumab ozogamicin	P9601	2820 mcg	4
	P9470	3384 mcg	2
Ipilimumab	P8555 P11930	120 mg	3
	P11391 P11478	120 mg	4
	P6562 P6585 P14808	360 mg	3
Irinotecan		800 mg	11
Methotrexate		250 mg	5
	P6276	20000 mg	0
Mitozantrone		30 mg	5
Nivolumab	P14830	120 mg	3
	P15471	360 mg	2
	P14001	360 mg	3
	P11985	360 mg	8
	P11468 P13433	360 mg	13
	P10119 P10120 P13900 P15527	480 mg	5
	P9216 P9312 P13445 P14816	480 mg	8

Listed Drug	Purposes	Maximum Amount	Number of Repeats
	P9252 P9298 P9299 P9321 P11477 P13839	480 mg	11
	P14676	480 mg	13
Nivolumab with relatlimab	P16188	480 mg	8
	P16151	480 mg	11
Obinutuzumab	P11785 P11787	1000 mg	5
	P11755 P14326 P14764	1000 mg	7
	P11015	1000 mg	8
	P11815	1000 mg	9
Oxaliplatin		300 mg	11
Paclitaxel		450 mg	3
Paclitaxel, nanoparticle albumin-bound	P4657	275 mg	11
	P6106 P6119	580 mg	5
Panitumumab	P12035 P12066	720 mg	5
	P5452 P5526	720 mg	9
Pembrolizumab	P14818	200 mg	5
	P13431 P13432	200 mg	6
	P10705 P14770 P14786	200 mg	7
	P14817	400 mg	2
	P10676 P10688 P10701 P13436 P13437	400 mg	3
	P13726 P13727 P13728 P13730 P13731 P13732 P13735 P13736 P13739 P13741 P13948 P13949 P14027 P14044 P14324 P14403 P14404	400 mg	6
	P14727	400 mg	7
Pemetrexed		1100 mg	5
Pertuzumab	P10414	420 mg	3
	P13018	840 mg	0
Pralatrexate	P7558	80 mg	5
	P7526	80 mg	11
Raltitrexed		7 mg	8

Clause 2

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Rituximab		800 mg	11
Sacituzumab govitecan	P12656	1200 mg	7
	P12669	1200 mg	13
Tebentafusp	P14813	20 mcg	0
	P14821	30 mcg	0
	P14825	68 mcg	0
	P15085	136 mcg	7
Topotecan		3500 mcg	17
Trabectedin	P14196	3250 mcg	3
	P14197	3250 mcg	7
Trastuzumab	P10213	250 mg	9
	P15831	500 mg	0
	P9349 P9571 P10294	750 mg	3
	P9353 P9573 P15820	1000 mg	0
Trastuzumab deruxtecan		675 mg	8
Trastuzumab emtansine	P15818 15819	450 mg	6
	P15827 P15828	450 mg	8
Vinblastine		20 mg	17
Vincristine		2 mg	7
Vinorelbine		70 mg	7

Schedule 2—Related pharmaceutical benefits

Note: See the definition of ***related pharmaceutical benefit*** in section 5, and sections 12, 15 and 17.

1 Related pharmaceutical benefits and related information

(1) Each pharmaceutical benefit specified in the following table is a related pharmaceutical benefit.

(2) The following table also specifies circumstances, purposes, maximum quantities and maximum repeats for related 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.

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
Aprepitant	Capsule 165 mg	Oral	Aprepitant APOTEX	C4216 C4223 C6383 C6464		1	5	
			APREPITANT SCP	C4216 C4223 C6383 C6464		1	5	
Atezolizumab	Solution for subcutaneous injection 1875 mg in 15 mL	Injection	Tecentriq SC	C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13443 C13448 C15455	P10206 P10939	1	3	
				C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13443 C13448 C15455	P10521	1	4	

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
				C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13443 C13448 C15455	P10125 P13443 P13448	1	5	
				C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13443 C13448 C15455	P10216 P10297 P15455	1	7	
				C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13443 C13448 C15455	P10917	1	8	
Daratumumab	Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL	Injection	Darzalex SC	C12691 C12845 C13752 C13774 C14015	P12845	1	4	
				C12691 C12845 C13752 C13774 C14015	P12691 P13774	1	5	
				C12691 C12845 C13752 C13774 C14015	P13752	1	8	
				C12691 C12845 C13752 C13774 C14015	P14015	1	15	
Folinic acid	Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL	Injection	Leucovorin Calcium (Pfizer Australia Pty Ltd)			10	2	

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
	Tablet containing calcium folinate equivalent to 15 mg folinic acid	Oral	Leucovorin Calcium (Hospira Pty Limited)	C5973		10	0	
Fosaprepitant	Powder for I.V. infusion 150 mg	Injection	Emend IV	C6852 C6886 C6887 C6891		1	5	
			FOSAPREPITANT MEDSURGE	C6852 C6886 C6887 C6891		1	5	
			FOSAPREPITANT MSN	C6852 C6886 C6887 C6891		1	5	
			FOSAPREPITANT-AFT	C6852 C6886 C6887 C6891		1	5	
Fosnetupitant with palonosetron	Solution concentrate for I.V. infusion containing fosnetupitant 235 mg (as chloride hydrochloride) and palonosetron 250 microgram (as hydrochloride)	Injection	Akynzeo IV	C14387		1	5	
Granisetron	Concentrated injection 3 mg (as hydrochloride) in 3 mL	Injection	Granisetron-AFT	C4139		1	0	V4139
			Kytril	C4139		1	0	V4139
	Tablet 2 mg (as hydrochloride)	Oral	Kytril	C4139		2	0	V4139
Mesna	Solution for I.V. injection 400 mg in 4 mL ampoule	Injection	Uromitexan	C5130		15	5	
	Solution for I.V. injection 1 g in 10 mL ampoule	Injection	Uromitexan	C5130		15	5	

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain	Single dose pack containing powder for irrigation 30 mg, 4 vials	Intravesical	VesiCulture	C5597		3	1	
Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain	Vial containing powder for intravesical administration approximately 5 x 10^8 CFU	Intravesical	OncoTICE	C5597		3	1	
Netupitant with Palonosetron	Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)	Oral	Akynzeo	C14443		1	5	
Ondansetron	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	Oral	Zofran syrup 50 mL	C5778		1	0	V5778
	Tablet (orally disintegrating) 4 mg	Oral	APX-Ondansetron ODT	C5743		4	0	V5743
			Ondansetron Mylan ODT	C5743		4	0	V5743
			Ondansetron ODT-DRLA	C5743		4	0	V5743
			Ondansetron ODT Viatris	C5743		4	0	V5743
			ONDANSETRON ODT-WGR	C5743		4	0	V5743
			Ondansetron SZ ODT	C5743		4	0	V5743

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
			Zotren ODT	C5743		4	0	V5743
	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	C5778		4	0	V5778
			APX-Ondansetron	C5778		4	0	V5778
			Ondansetron-DRL A	C5778		4	0	V5778
			Ondansetron Mylan Tablets	C5778		4	0	V5778
			Ondansetron SZ	C5778		4	0	V5778
			Ondansetron Tablets Viatris	C5778		4	0	V5778
			ONDANSETRON-WGR	C5778		4	0	V5778
			Zofran	C5778		4	0	V5778
			Zotren 4	C5778		4	0	V5778
	Tablet (orally disintegrating) 8 mg	Oral	APX-Ondansetron ODT	C5743		4	0	V5743
			Ondansetron Mylan ODT	C5743		4	0	V5743
			Ondansetron ODT-DRLA	C5743		4	0	V5743
			Ondansetron ODT Viatris	C5743		4	0	V5743

Clause 1

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
			ONDANSETRON ODT-WGR	C5743		4	0	V5743
			Ondansetron SZ ODT	C5743		4	0	V5743
			Zotren ODT	C5743		4	0	V5743
	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	C5778		4	0	V5778
			APX-Ondansetron	C5778		4	0	V5778
			Ondansetron-DRL A	C5778		4	0	V5778
			Ondansetron Mylan Tablets	C5778		4	0	V5778
			Ondansetron SZ	C5778		4	0	V5778
			Ondansetron Tablets Viatris	C5778		4	0	V5778
			ONDANSETRON-WGR	C5778		4	0	V5778
			Zofran	C5778		4	0	V5778
			Zotren 8	C5778		4	0	V5778
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	Aloxi	C5805		1	0	
			Palonosetron Dr.Reddy's	C5805		1	0	

Listed Drug	Form	Manner of Administration	Brand	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Variation
			PALONOSETRON Medsurge	C5805		1	0	
Trastuzumab	Solution for subcutaneous injection containing trastuzumab 600 mg in 5 mL	Injection	Herceptin SC	C9353 C9462 C10212	P9353	1	0	
				C9353 C9462 C10212	P9462 P10212	1	3	

Schedule 3—Circumstances, purposes and variations

Note: See sections 12 to 18 and 23.

Part 1—Circumstances and purposes

1 Circumstances and purposes

The following table sets out:

(a) circumstances for circumstances codes, for the purposes of sections 12 and 23; and

(b) purposes for purposes codes, for the purposes of sections 14 to 17; and

(c) for the purposes of section 13, information relating to how authorisation is obtained when the circumstances for writing a prescription include an authorisation requirement.

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C4139		Granisetron	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.	

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C4216		Aprepitant	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4216
C4223		Aprepitant	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4223
C4649	P4649	Eribulin	Locally advanced or metastatic breast cancer Patient must have progressive disease; AND Patient must have failed at least two prior chemotherapeutic regimens for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 4649
C4657	P4657	Paclitaxel, nanoparticle albumin-bound	Stage IV (metastatic) adenocarcinoma of the pancreas The treatment must be in combination with gemcitabine; AND The condition must not have been treated previously with PBS-subsidised therapy; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less. 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 - Streamlined Authority Code 4657

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C4785	P4785	Cetuximab	Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Initial treatment The treatment must be in combination with radiotherapy; AND Patient must be unable to tolerate cisplatin.	Compliance with Authority Required procedures - Streamlined Authority Code 4785
C4788	P4788	Cetuximab	Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Continuing treatment The treatment must be in combination with radiotherapy; AND Patient must be unable to tolerate cisplatin; OR Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.	Compliance with Authority Required procedures - Streamlined Authority Code 4788
C4793	P4793	Arsenic	Acute promyelocytic leukaemia Induction and consolidation treatment The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript; AND The condition must be relapsed; AND Patient must be arsenic naive at induction.	Compliance with Authority Required procedures - Streamlined Authority Code 4793
C4794	P4794	Cetuximab	Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Initial treatment The treatment must be for the week prior to radiotherapy; AND Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.	Compliance with Authority Required procedures - Streamlined Authority Code 4794
C4908	P4908	Cetuximab	Metastatic colorectal cancer Initial treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must be previously untreated; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 4908

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C4912	P4912	Cetuximab	Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for this drug for first-line treatment of RAS wild-type metastatic colorectal cancer; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 4912
C5130		Mesna	Urothelial toxicity Prophylaxis or reduction of toxicity The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.	
C5452	P5452	Panitumumab	Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for panitumumab for first-line treatment of RAS wild-type metastatic colorectal cancer; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.	Compliance with Authority Required procedures - Streamlined Authority Code 5452
C5526	P5526	Panitumumab	Metastatic colorectal cancer Initial Treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must be previously untreated; AND The treatment must be in combination with first-line chemotherapy; AND	Compliance with Authority Required procedures - Streamlined Authority Code 5526

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.	
C5597		Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain	Primary and relapsing superficial urothelial carcinoma of the bladder	
C5743		Ondansetron	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.	
C5778		Ondansetron	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.	
C5805		Palonosetron	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.	
C5973		Folinic acid	Megaloblastic anaemias The condition must be a result of folic acid deficiency from the use of folic acid antagonists.	
C5997	P5997	Arsenic	Acute promyelocytic leukaemia The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript.	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
				Code 5997
C6018	P6018	Arsenic	Acute promyelocytic leukaemia Induction and consolidation treatment The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript.	Compliance with Authority Required procedures - Streamlined Authority Code 6018
C6106	P6106	Paclitaxel, nanoparticle albumin-bound	Metastatic breast cancer	Compliance with Authority Required procedures - Streamlined Authority Code 6106
C6119	P6119	Paclitaxel, nanoparticle albumin-bound	HER2 positive breast cancer	Compliance with Authority Required procedures - Streamlined Authority Code 6119
C6224		Bleomycin	Lymphoma	
C6247		Idarubicin	Acute myelogenous leukaemia (AML)	
C6265		Cladribine	Hairy cell leukaemia	Compliance with Authority Required procedures - Streamlined Authority Code 6265
C6266	P6266	Fluorouracil	Patients requiring administration of fluorouracil by intravenous infusion	
C6275		Bleomycin	Germ cell neoplasms	
	P6276	Methotrexate	Patients receiving treatment with a high dose regimen	
C6297	P6297	Fluorouracil	Patients requiring administration of fluorouracil by intravenous injection	
C6383		Aprepitant	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND	Compliance with Authority Required procedures - Streamlined Authority Code 6383

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	
C6464		Aprepitant	Nausea and vomiting The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 6464
C6562	P6562	Ipilimumab	Unresectable Stage III or Stage IV malignant melanoma Induction treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior treatment with ipilimumab; AND The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 6562
C6585	P6585	Ipilimumab	Unresectable Stage III or Stage IV malignant melanoma	Compliance with Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Re-induction treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction); AND The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. An initial objective response to treatment is defined as either: (i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or (ii) a partial or complete response. The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.	Required procedures - Streamlined Authority Code 6585
C6852		Fosaprepitant	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 6852

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C6886		Fosaprepitant	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6886
C6887		Fosaprepitant	Nausea and vomiting The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 6887

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C6891		Fosaprepitant	Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6891
C7258	P7258	Eribulin	Advanced (unresectable and/or metastatic) liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype; AND Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition; 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 7258
C7280	P7280	Eribulin	Advanced (unresectable and/or metastatic) liposarcoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop progressive disease while being treated with this drug for this condition; 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 7280

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C7526	P7526	Pralatrexate	Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma Continuing treatment The condition must be relapsed or chemotherapy refractory; AND Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
C7558	P7558	Pralatrexate	Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma Initial treatment The condition must be relapsed or chemotherapy refractory; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy.	Compliance with Authority Required procedures
C7943		Bendamustine	Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma Induction treatment The condition must be CD20 positive; AND The condition must be previously untreated; AND The condition must be symptomatic; AND The treatment must be for induction treatment purposes only; AND The treatment must be in combination with rituximab or obinutuzumab; AND The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 7943
C7944		Bendamustine	Follicular lymphoma Re-induction treatment The condition must be CD20 positive; AND The condition must be refractory to treatment with rituximab for this condition; AND The condition must be symptomatic; AND The treatment must be for re-induction treatment purposes only; AND The treatment must be in combination with obinutuzumab; AND The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 7944

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.	
C7972		Bendamustine	Previously untreated stage III or IV mantle cell lymphoma Induction treatment The condition must be CD20 positive; AND The treatment must be in combination with rituximab; AND The condition must be previously untreated; AND The condition must be symptomatic; AND The treatment must be for induction treatment purposes only; AND Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction; AND Patient must not be eligible for stem cell transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 7972
C8555	P8555	Ipilimumab	Stage IV clear cell variant renal cell carcinoma (RCC) Induction treatment The condition must not have previously been treated; AND The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND Patient must have a WHO performance status of 2 or less; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 8555

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C9216	P9216	Nivolumab	Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Initial treatment Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 9216
C9252	P9252	Nivolumab	Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 9252
C9298	P9298	Nivolumab	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must have stable or responding disease. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 9298

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C9299	P9299	Nivolumab	Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 9299
C9312	P9312	Nivolumab	Stage IV clear cell variant renal cell carcinoma (RCC) Initial Treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; OR Patient must have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 9312

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C9321	P9321	Nivolumab	Stage IV clear cell variant renal cell carcinoma (RCC) Maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND The treatment must be as monotherapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 9321
C9349	P9349	Trastuzumab	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, a new loading dose may be required.	Compliance with Authority Required procedures - Streamlined Authority Code 9349
C9353	P9353	Trastuzumab	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion; AND The treatment must not be in combination with nab-paclitaxel; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA),	Compliance with Authority Required procedures - Streamlined Authority Code 9353

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			prior to initiating treatment with this drug for this condition.	
C9369	P9369	Blinatumomab	Acute lymphoblastic leukaemia Consolidation treatment Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND Patient must have achieved a complete remission; OR Patient must have achieved a complete remission with partial haematological recovery; AND The treatment must not be more than 3 treatment cycles under this restriction in a lifetime; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.	Compliance with Authority Required procedures
C9462	P9462	Trastuzumab	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.	Compliance with Authority Required procedures - Streamlined Authority Code 9462
C9470	P9470	Inotuzumab ozogamicin	Acute lymphoblastic leukaemia Induction treatment The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND Patient must not have received more than 1 line of salvage therapy; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND The condition must be CD22-positive; AND The condition must have more than 5% blasts in bone marrow; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must not be more than 3 treatment cycles under this restriction in a lifetime. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include: (1) two completed authority prescription forms; (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) evidence that the condition is CD22-positive; and (4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application. The treatment must not exceed 0.8mg per m2for the first dose of a treatment cycle (Day 1), and 0.5mg per m2for subsequent doses (Days 8 and 15) within a treatment cycle. Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.	

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C9519	P9519	Blinatumomab	Acute lymphoblastic leukaemia Induction treatment - balance of supply The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND The condition must not be present in the central nervous system or testis; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures
C9571	P9571	Trastuzumab	Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.	Compliance with Authority Required procedures - Streamlined Authority Code 9571

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C9573	P9573	Trastuzumab	Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity as demonstrated by immunohistochemistry 2+ or more in tumour material; AND Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on more than 6 copies of HER2 in the same tumour tissue sample; AND Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on the ratio of HER2 to chromosome 17 being more than 2 in the same tumour tissue sample; AND Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; OR Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil; AND Patient must not have previously received this drug for this condition; AND Patient must not have received prior chemotherapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9573
C9601	P9601	Inotuzumab ozogamicin	Acute lymphoblastic leukaemia Consolidation treatment Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND Patient must have achieved a complete remission; OR Patient must have achieved a complete remission with partial haematological recovery; AND The treatment must not be more than 5 treatment cycles under this restriction in a lifetime; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			while on this drug. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The treatment must not exceed 0.5mg per m2for all doses within a treatment cycle Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.	
C10119	P10119	Nivolumab	Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma Initial treatment The treatment must be adjuvant to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures
C10120	P10120	Nivolumab	Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C10125	P10125	Atezolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment 2 Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy. The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND Patient must have a WHO performance status of 0 or 1; AND Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material; AND Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI); AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 10125
C10206	P10206	Atezolizumab Durvalumab	Extensive-stage small cell lung cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.	Compliance with Authority Required procedures - Streamlined Authority Code 10206

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C10212	P10212	Trastuzumab	Early HER2 positive breast cancer 3 weekly treatment regimen Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10212
C10213	P10213	Trastuzumab	Early HER2 positive breast cancer Continuing treatment (weekly regimen) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.	Compliance with Authority Required procedures - Streamlined Authority Code 10213
C10215	P10215	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Continuing treatment - 4 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10215

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C10216	P10216	Atezolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated. Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10216
C10257	P10257	Atezolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing first-line treatment of metastatic disease, as monotherapy, where concomitant bevacizumab has ceased due to intolerance - 4 weekly treatment regimen Patient must have experienced intolerance to combination treatment with bevacizumab; AND Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND Patient must have stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10257
C10294	P10294	Trastuzumab	Early HER2 positive breast cancer Continuing treatment (3 weekly regimen) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.	Compliance with Authority Required procedures - Streamlined Authority Code 10294
C10297	P10297	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Continuing treatment - 3 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition;	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have stable or responding disease.	Code 10297
C10414	P10414	Pertuzumab	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be in combination with trastuzumab; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one course. However, treatment breaks are permitted. A patient who has a treatment break in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.	Compliance with Authority Required procedures
C10509	P10509	Atezolizumab Durvalumab	Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10509
C10521	P10521	Atezolizumab	Extensive-stage small cell lung cancer	Compliance with Authority

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Continuing treatment - 3 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Required procedures - Streamlined Authority Code 10521
C10676	P10676	Pembrolizumab	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 6 weekly treatment regimen Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	Compliance with Authority Required procedures
C10688	P10688	Pembrolizumab	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 6 weekly treatment regimen The treatment must be adjuvant to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C10701	P10701	Pembrolizumab	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment - 6 weekly treatment regimen The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10701
C10705	P10705	Pembrolizumab	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment - 3 weekly treatment regimen The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10705
C10917	P10917	Atezolizumab	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time	Compliance with Authority Required procedures - Streamlined Authority Code 10917
C10939	P10939	Atezolizumab	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Initial treatment Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.	Compliance with Authority Required procedures - Streamlined Authority Code 10939

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have a WHO performance status of 0 or 1; AND Patient must not be suitable for transarterial chemoembolisation; AND Patient must have Child Pugh class A; AND The condition must be untreated with systemic therapy; OR Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.	
C10972	P10972	Atezolizumab	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time	Compliance with Authority Required procedures - Streamlined Authority Code 10972
C11015	P11015	Obinutuzumab	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy The condition must be untreated; AND The treatment must be in combination with PBS-subsidised venetoclax.	Compliance with Authority Required procedures - Streamlined Authority Code 11015
C11099		Bortezomib	Multiple myeloma	
C11391	P11391	Ipilimumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing combination treatment (with nivolumab) of first-line drug therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not	Compliance with Authority Required procedures - Streamlined Authority Code 11391

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			extend beyond disease progression, whichever comes first; AND The treatment must be in combination with nivolumab.	
C11468	P11468	Nivolumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing combination treatment (with ipilimumab) of first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND The treatment must be in combination with ipilimumab.	Compliance with Authority Required procedures - Streamlined Authority Code 11468
C11477	P11477	Nivolumab	Locally advanced or metastatic non-small cell lung cancer Continuing treatment as second-line drug therapy Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have stable or responding disease. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 11477
C11478	P11478	Ipilimumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial combination treatment (with nivolumab) as first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1	Compliance with Authority Required procedures - Streamlined Authority Code 11478

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(ROS1) gene arrangement in tumour material; AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with nivolumab. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	
C11755	P11755	Obinutuzumab	Follicular lymphoma Re-induction treatment Patient must not have previously received PBS-subsidised obinutuzumab; AND The condition must be CD20 positive; AND The condition must be refractory to treatment with rituximab for this condition; AND The condition must be symptomatic; AND The treatment must be for re-induction treatment purposes only; AND The treatment must be in combination with bendamustine; AND The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition. The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen. A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under: i) the previously untreated induction treatment restriction; or ii) the rituximab-refractory re-induction restriction.	Compliance with Authority Required procedures
C11785	P11785	Obinutuzumab	Follicular lymphoma Maintenance therapy Patient must have previously received PBS-subsidised treatment with this drug under the rituximab refractory initial restriction; AND The condition must be CD20 positive; AND The condition must have been refractory to treatment with rituximab; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have demonstrated a partial or complete response to PBS-subsidised re-induction treatment with this drug for this condition; AND The treatment must be maintenance therapy; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
C11787	P11787	Obinutuzumab	Stage II bulky or Stage III/IV follicular lymphoma Maintenance therapy Patient must have previously received PBS-subsidised treatment with this drug under the previously untreated initial restriction; AND The condition must be CD20 positive; AND Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition; AND The treatment must be maintenance therapy; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C11815	P11815	Obinutuzumab	Stage II bulky or Stage III/IV follicular lymphoma Induction treatment The condition must be CD20 positive; AND The condition must be previously untreated; AND The condition must be symptomatic; AND The treatment must be for induction treatment purposes only; AND The treatment must be in combination with chemotherapy; AND The treatment must not exceed 10 doses for induction treatment with this drug for this condition. A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under: i) the previously untreated induction treatment restriction; or ii) the rituximab-refractory re-induction restriction.	Compliance with Authority Required procedures
C11930	P11930	Ipilimumab	Unresectable malignant mesothelioma Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with PBS-subsidised nivolumab for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 11930
C11985	P11985	Nivolumab	Unresectable malignant mesothelioma Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with PBS-subsidised ipilimumab, unless an intolerance to ipilimumab of a severity necessitating permanent treatment withdrawal of ipilimumab; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a maximum total of 24 months in a lifetime for this condition. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 11985

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C12016	P12016	Cetuximab	Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; OR Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC; AND Patient must not have progressive disease; AND The treatment must be as monotherapy; OR The treatment must be in combination with chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab. Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.	Compliance with Authority Required procedures - Streamlined Authority Code 12016
C12035	P12035	Panitumumab	Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; OR Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC; AND Patient must not have progressive disease; AND The treatment must be as monotherapy; OR The treatment must be in combination with chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.	Compliance with Authority Required procedures - Streamlined Authority Code 12035

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.	
C12045	P12045	Cetuximab	Metastatic colorectal cancer Initial treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 2 or less; AND The condition must have failed to respond to first-line chemotherapy; OR The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND The treatment must be as monotherapy; OR The treatment must be in combination with chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab. Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.	Compliance with Authority Required procedures - Streamlined Authority Code 12045
C12066	P12066	Panitumumab	Metastatic colorectal cancer Initial treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 2 or less; AND The condition must have failed to respond to first-line chemotherapy; OR The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND The treatment must be as monotherapy; OR The treatment must be in combination with chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised	Compliance with Authority Required procedures - Streamlined Authority Code 12066

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			panitumumab. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.	
C12271	P12271	Durvalumab	Unresectable Stage III non-small cell lung cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 months in total for this condition under the initial and continuing restriction combined; AND The treatment must be once in a lifetime with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12271
C12470	P12470	Cetuximab	Metastatic colorectal cancer Continuing treatment The treatment must be in combination with PBS-subsidised encorafenib for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12470
C12483	P12483	Cetuximab	Metastatic colorectal cancer Initial treatment The treatment must be in combination with PBS-subsidised encorafenib for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12483
C12559	P12559	Gemtuzumab ozogamicin	Acute Myeloid Leukaemia Induction treatment Patient must have confirmed CD33-positive AML prior to initiation of treatment; AND The condition must be de novo; AND The condition must be previously untreated at the time of initiation (except for prior essential treatment with hydroxyurea or leukapheresis for patients with hyperleukocytic AML); AND Patient must have confirmed intermediate/favourable cytogenetic risk; OR	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have unknown cytogenetic risk due to inconclusive test results; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The condition must not be acute promyelocytic leukaemia; AND The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline; AND The treatment must not be used in combination with a tyrosine kinase inhibitor; AND The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive; AND Patient must not receive more than 1 induction cycle under this restriction in a lifetime. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.	
C12566	P12566	Gemtuzumab ozogamicin	Acute Myeloid Leukaemia Consolidation treatment Patient must have achieved a complete remission following induction treatment with this drug for this condition; AND The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline; AND Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. Complete remission following induction is defined as fewer than 5% blasts in a normocellular marrow and an absolute neutrophil count of more than 1.0 x 109cells/L with a platelet count of 100 x 109/L or more in the peripheral blood in the absence of transfusion. Progressive disease is defined as the presence of any of the following: a) Leukaemic cells in the CSF; b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; d) Extramedullary leukaemia.	
C12656	P12656	Sacituzumab govitecan	Unresectable locally advanced or metastatic triple-negative breast cancer Initial treatment Patient must have progressive disease following two or more prior systemic therapies, at least one of them in the locally advanced or metastatic setting; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND The treatment must be the sole PBS-subsidised therapy for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 12656
C12669	P12669	Sacituzumab govitecan	Unresectable locally advanced or metastatic triple-negative breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 12669
C12691	P12691	Daratumumab	Relapsed and/or refractory multiple myeloma Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. 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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(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.	
C12694	P12694	Carfilzomib	Multiple myeloma Initial treatment - once weekly treatment regimen The condition must be confirmed by a histological diagnosis; AND 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 stem cell transplant; AND Patient must not have previously received this drug for this condition; AND Patient must not receive more than three cycles of treatment under this restriction. 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	Compliance with Authority Required procedures - Streamlined Authority Code 12694

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(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.	
C12845	P12845	Daratumumab	Relapsed and/or refractory multiple myeloma Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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.	
C12847	P12847	Elotuzumab	Relapsed and/or refractory multiple myeloma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures
C12849	P12849	Carfilzomib	Multiple myeloma Continuing treatment - once weekly treatment regimen	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with dexamethasone; AND Patient must not develop disease progression while receiving treatment with this drug for this condition; AND Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction. 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.	Code 12849
C12930	P12930	Carfilzomib	Multiple myeloma Continuing treatment - twice weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with dexamethasone; AND Patient must not develop disease progression while receiving treatment with this drug for this	Compliance with Authority Required procedures - Streamlined Authority Code 12930

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			condition; AND Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction. 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.	
C12934	P12934	Carfilzomib	Multiple myeloma Initial treatment - twice weekly treatment regimen The condition must be confirmed by a histological diagnosis; AND 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 stem cell transplant; AND Patient must not have previously received this drug for this condition; AND Patient must not receive more than three cycles of treatment under this restriction. Progressive disease is defined as at least 1 of the following:	Compliance with Authority Required procedures - Streamlined Authority Code 12934

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(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.	
C13018	P13018	Pertuzumab	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND Patient must have a WHO performance status of 0 or 1; AND Patient must not have received prior anti-HER2 therapy for this condition; AND Patient must not have received prior chemotherapy for this condition; AND The treatment must be in combination with trastuzumab and a taxane; AND The treatment must not be in combination with nab-paclitaxel; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			or a metastatic lesion by in situ hybridisation (ISH) must be provided at the time of application. The pathology report must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.	
C13134	P13134	Brentuximab vedotin	CD30 positive peripheral T-cell lymphoma, non-cutaneous type Initial treatment Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells; AND The treatment must be for first line therapy for this condition; AND The treatment must be for curative intent; AND The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND The treatment must not be more than 6 treatment cycles under this restriction in a lifetime. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and (b) The date of initial diagnosis of Peripheral T-cell lymphoma. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
C13179	P13179	Brentuximab vedotin	CD30 positive cutaneous T-cell lymphoma Initial treatment Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma; AND Patient must have CD30 positivity of at least 3% of malignant cells; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have a diagnosis of mycosis fungoides; OR Patient must have a diagnosis of Sezary syndrome; OR Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma; AND Patient must have received prior systemic treatment for this condition; AND The condition must be relapsed or refractory; AND The treatment must not exceed 4 cycles under this restriction in a lifetime; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and (b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and (c) Date of commencement and completion of the most recent prior systemic treatment. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13181	P13181	Brentuximab vedotin	CD30 positive cutaneous T-cell lymphoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved an objective response with this drug; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime. An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.	
C13182	P13182	Brentuximab vedotin	CD30 positive systemic anaplastic large cell lymphoma Initial treatment The treatment must be for curative intent; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND Patient must demonstrate relapsed or chemotherapy-refractory disease; AND Patient must have responded to PBS-subsidised treatment with this drug if previously used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type; AND The treatment must not exceed 4 cycles under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and (b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and (c) Dates of commencement and completion of front-line curative intent chemotherapy; and (d) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
C13207		Cabazitaxel	Castration resistant metastatic carcinoma of the prostate The treatment must be in combination with prednisone or prednisolone; AND	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The condition must be resistant to treatment with docetaxel; OR Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel; AND The treatment must not be used in combination with a novel hormonal drug; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.	Streamlined Authority Code 13207
C13208	P13208	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND 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 not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.	Compliance with Authority Required procedures
C13209	P13209	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; OR Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; AND Patient must not receive more than 4 cycles of treatment under this restriction.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13212	P13212	Brentuximab vedotin	CD30 positive peripheral T-cell lymphoma, non-cutaneous type Continuing treatment The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication; AND Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as: (a) Positron emission tomography-based response: lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR (b) Computed tomography-based response: lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C13231	P13231	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND 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 not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.	Compliance with Authority Required procedures
C13259	P13259	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone a primary autologous stem cell transplant (ASCT); AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; OR Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
C13261	P13261	Brentuximab vedotin	CD30 positive systemic anaplastic large cell lymphoma Continuing treatment Patient must not have developed disease progression while receiving PBS-subsidised treatment with	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime.	
C13290	P13290	Avelumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated 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 13290
C13411	P13411	Cemiplimab	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) 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. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	Compliance with Authority Required procedures
C13419	P13419	Cemiplimab	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) Initial treatment covering the first 3 treatment cycles The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy; AND Patient must have had a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures
C13431	P13431	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 7 doses under this restriction.	Code 13431
C13432	P13432	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 3 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	Compliance with Authority Required procedures - Streamlined Authority Code 13432
C13433	P13433	Nivolumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial combination treatment (with ipilimumab) as first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13433

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with ipilimumab.	
C13436	P13436	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 6 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 4 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 13436
C13437	P13437	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 6 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	Compliance with Authority Required procedures - Streamlined Authority Code 13437
C13442	P13442	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,200 mg administered once every 3 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug,	Compliance with Authority Required procedures - Streamlined Authority Code 13442

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	
C13443	P13443	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; OR The condition must have progressed after treatment with tepotinib.	Compliance with Authority Required procedures - Streamlined Authority Code 13443
C13445	P13445	Nivolumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment as second-line drug therapy Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a	Compliance with Authority Required procedures - Streamlined Authority Code 13445

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; OR The condition must have progressed after treatment with tepotinib. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	
C13446	P13446	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment - 4 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; OR The condition must have progressed after treatment with tepotinib.	Compliance with Authority Required procedures - Streamlined Authority Code 13446
C13448	P13448	Atezolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment 1 Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy. The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13448

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.	
C13451	P13451	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,680 mg administered once every 4 weeks, or 840 mg every 2 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	Compliance with Authority Required procedures - Streamlined Authority Code 13451
C13726	P13726	Pembrolizumab	Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; OR	Compliance with Authority Required procedures - Streamlined Authority Code 13726

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition; AND Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C13727	P13727	Pembrolizumab	Relapsed or refractory primary mediastinal B-cell lymphoma Initial treatment The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan; AND Patient must have been treated with rituximab-based chemotherapy for this condition; AND Patient must be experiencing relapsed/refractory disease; AND Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; OR Patient must have undergone an autologous stem cell transplant (ASCT); OR Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 13727

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C13728	P13728	Pembrolizumab	Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer Initial treatment Patient must be untreated for this PBS indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease); AND Patient must not have received prior treatment for colorectal cancer with each of: (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor; AND Patient must have a WHO performance status of 0 or 1; AND Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures
C13730	P13730	Pembrolizumab	Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures
C13731	P13731	Pembrolizumab	Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition;	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			AND	Code 13731
			Patient must not have developed disease progression while being treated with this drug for this condition.	
			Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR	
			Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND	
			Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	
C13732	P13732	Pembrolizumab	Relapsed or refractory primary mediastinal B-cell lymphoma	Compliance with Authority Required procedures - Streamlined Authority Code 13732
			Continuing treatment	
			Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	
			Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
			Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR	
			Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND	
			Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	
C13735	P13735	Pembrolizumab	Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx	Compliance with Authority Required procedures - Streamlined Authority Code 13735
			Initial treatment	
			The condition must be incurable by local therapies in the locally advanced setting; AND	
			Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating PBS-subsidised treatment with this drug for this condition; AND	
			Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if previously treated in the locally advanced setting; AND	

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have had a WHO performance status of 0 or 1; AND The treatment must be either: (i) the sole PBS-subsidised therapy where the condition expresses programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) greater than or equal to 20 in the tumour sample, (ii) in combination with platinum-based chemotherapy, unless contraindicated or not tolerated. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C13736	P13736	Pembrolizumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 13736
C13739	P13739	Pembrolizumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy; OR The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial	Compliance with Authority Required procedures - Streamlined Authority Code 13739

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			cancer; OR The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C13741	P13741	Pembrolizumab	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 13741
C13745		Bortezomib	Newly diagnosed systemic light chain amyloidosis Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.	
C13752	P13752	Daratumumab	Relapsed and/or refractory multiple myeloma	Compliance with Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly) The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised). Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication. 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. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.	Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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 must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	
C13774	P13774	Daratumumab	Newly diagnosed systemic light chain amyloidosis Continuing treatment from week 25 onwards (administered once every four weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.	
C13839	P13839	Nivolumab	Unresectable Stage III or Stage IV malignant melanoma Maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND The treatment must be as monotherapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this PBS indication. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 13839
C13900	P13900	Nivolumab	Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer The condition must have histological evidence confirming a diagnosis of a least one of: (i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records; AND The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy; AND The treatment must be for the purposes of adjuvant use following complete surgical resection that occurred within 16 weeks prior to initiating this drug; AND The condition must have evidence, through resected specimen, that residual disease meets the Tumour Nodes Metastases (TNM) staging system (as published by the Union for International Cancer Control) of either: (i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information; AND Patient must not be undergoing PBS-subsidised treatment with this drug where this prescription extends treatment beyond whichever comes first: (i) 12 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease recurrence despite treatment with this drug; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	
C13948	P13948	Pembrolizumab	Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND The condition must be untreated; AND Patient must have a WHO performance status of 2 or less. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 13948
C13949	P13949	Pembrolizumab	Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13949

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	
C14001	P14001	Nivolumab	Stage IV clear cell variant renal cell carcinoma (RCC) Induction treatment The condition must not have previously been treated; AND Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 14001
C14015	P14015	Daratumumab	Newly diagnosed systemic light chain amyloidosis Initial treatment from week 0 to week 24 The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must be untreated with drug therapy, including this drug, irrespective of whether the	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C14027	P14027	Pembrolizumab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up	Compliance with Authority Required procedures - Streamlined Authority Code 14027

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
C14044	P14044	Pembrolizumab	Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 14044
C14196	P14196	Trabectedin	Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 14196
C14197	P14197	Trabectedin	Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma	Compliance with Authority

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Required procedures - Streamlined Authority Code 14197
C14324	P14324	Pembrolizumab	Recurrent, unresectable or metastatic triple negative breast cancer The condition must have been (up until this drug therapy) untreated in the unresectable/metastatic disease stage; AND The condition must have been (up until this drug therapy) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy in breast cancer; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND The treatment must be in combination with chemotherapy; AND The condition must have both: (i) programmed cell death ligand 1 (PD-L1) expression confirmed by a validated test, (ii) a Combined Positive Score (CPS) of at least 10 at treatment initiation. Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR Patient must be undergoing continuing treatment with this drug - both the following are true: (i) the condition has not progressed on active treatment with this drug, (ii) this prescription does not extend PBS subsidy beyond 24 cumulative months from the first administered dose; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14324
C14326	P14326	Obinutuzumab	Chronic lymphocytic leukaemia (CLL) Combination use with chlorambucil only	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The condition must be CD20 positive; AND The condition must be previously untreated; AND The treatment must be in combination with chlorambucil; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition. Treatment must be discontinued in patients who experience disease progression whilst on this treatment.	Code 14326
C14363	P14363	Carfilzomib	Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 3 to 12 Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).	Compliance with Authority Required procedures - Streamlined Authority Code 14363

Clause 1

Circumstances Code	Purposes Code	Listed Drug	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.	
C14364	P14364	Carfilzomib	Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 13 onwards Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	Compliance with Authority Required procedures - Streamlined Authority Code 14364
C14387		Fosnetupitant with palonosetron	Nausea and vomiting The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy; AND The treatment must be in combination with dexamethasone, unless contraindicated; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must be unable to swallow; OR Patient must be contraindicated to oral anti-emetics.	
C14389	P14389	Carfilzomib	Relapsed and/or refractory multiple myeloma Initial treatment for Cycles 1 to 3 The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Provide details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of the most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response once only through the Authority application for lenalidomide.	Compliance with Authority Required procedures - Streamlined Authority Code 14389

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C14403	P14403	Pembrolizumab	Advanced carcinoma of the cervix Initial treatment The condition must be at least one of (i) persistent carcinoma, (ii) recurrent carcinoma, (iii) metastatic carcinoma of the cervix; AND The condition must be unsuitable for curative treatment with either of (i) surgical resection, (ii) radiation; AND Patient must have WHO performance status no higher than 1; AND Patient must not have received prior treatment for this PBS indication. Patient must be undergoing concomitant treatment with chemotherapy, containing a minimum of: (i) a platinum-based chemotherapy agent, plus (ii) paclitaxel; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14403
C14404	P14404	Pembrolizumab	Advanced carcinoma of the cervix Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14404
C14416		Enfortumab vedotin	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	Compliance with Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The condition must have progressed on/following both: (i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR The condition must have progressed on/following platinum-based chemotherapy, whilst PD-1/PD-L1 inhibitor therapy resulted in an intolerance that required treatment cessation; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must be undergoing treatment with this drug for the first time; OR Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.	Required procedures - Streamlined Authority Code 14416
C14443		Netupitant with Palonosetron	Nausea and vomiting The treatment must be in combination with dexamethasone, unless contraindicated; AND The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 14443
C14587	P14587	Blinatumomab	Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Continuing treatment of previously measurable residual disease of Pre-B-cell ALL Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have achieved a complete remission; AND The condition must be negative for measurable residual disease using the same method used to determine initial PBS eligibility; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. 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.	
C14588	P14588	Blinatumomab	Acute lymphoblastic leukaemia Induction treatment The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND The condition must not be present in the central nervous system or testis; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND Patient must not have received more than 1 line of salvage therapy; AND The condition must be one of the following: (i) untreated with this drug for measurable residual disease, (ii) treated with this drug for measurable residual disease, but the condition has not relapsed within 6 months of completing that course of treatment; AND The condition must have more than 5% blasts in bone marrow; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(1) a completed authority prescription form; and (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (4) if applicable, the date of completion of blinatumomab treatment for measurable residual disease and the date of the patient's subsequent relapse; and (5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.	
C14631	P14631	Blinatumomab	Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Initial treatment of measurable residual disease of Pre-B-cell ALL Must be treated by a physician experienced in the treatment of haematological malignancies. Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be present in the central nervous system or testis; AND Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND Patient must have measurable residual disease based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Measurable residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and (4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. 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.	
C14676	P14676	Nivolumab	Advanced or metastatic gastro-oesophageal cancers Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. Patient must be in one of the three population subsets described below. Population 1 Conditions: gastric cancer, gastro-oesophageal junction cancer, oesophageal adenocarcinoma Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: HER2 negative Population 2 Condition: oesophageal squamous cell carcinoma (can be recurrent)	Compliance with Authority Required procedures - Streamlined Authority Code 14676

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: unresectable Population 3 Condition: oesophageal squamous cell carcinoma (can be recurrent) Line of treatment: second-line drug treatment after chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Additional clinical finding: unresectable	
C14708	P14708	Durvalumab	Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer) Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14708
C14727	P14727	Pembrolizumab	Stage II or Stage III triple negative breast cancer The treatment must be initiated in combination with neoadjuvant chemotherapy; AND The condition must not have progressed/recurred whilst on treatment with this drug. Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up	Compliance with Authority Required procedures - Streamlined Authority Code 14727

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			to 4 repeat prescriptions.	
C14764	P14764	Obinutuzumab	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy The condition must be untreated; AND The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses).	Compliance with Authority Required procedures - Streamlined Authority Code 14764
C14770	P14770	Pembrolizumab	Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 3 weekly treatment regimen The treatment must be in addition to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).	Compliance with Authority Required procedures
C14786	P14786	Pembrolizumab	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 3 weekly treatment regimen Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing. Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).	Compliance with Authority Required procedures
C14808	P14808	Ipilimumab	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant	Compliance with Authority Required procedures - Streamlined Authority Code 14808

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	
C14813	P14813	Tebentafusp	Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 1 Patient must have HLA-A*02:01-positive disease; AND Patient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior systemic therapy for metastatic disease. Patient must be at least 18 years of age. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02:01 assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
C14816	P14816	Nivolumab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 14816
C14817	P14817	Pembrolizumab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 6 weekly treatment regimen Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 3 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14817
C14818	P14818	Pembrolizumab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated	Compliance with Authority Required procedures - Streamlined Authority Code 14818

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 6 doses under this restriction.	
C14821	P14821	Tebentafusp	Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 8 Patient must have HLA-A*02:01-positive disease; AND Patient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02:01 assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14821
C14825	P14825	Tebentafusp	Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 15 Patient must have HLA-A*02:01-positive disease; AND Patient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes	Compliance with Authority Required procedures - Streamlined Authority Code 14825

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02:01 assessment must be documented in the patient's medical records.	
C14830	P14830	Nivolumab	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	Compliance with Authority Required procedures - Streamlined Authority Code 14830
C15063	P15063	Cemiplimab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 3 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	Compliance with Authority Required procedures - Streamlined Authority Code 15063
C15085	P15085	Tebentafusp	Advanced (unresectable or metastatic) uveal melanoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must have previously received inpatient treatment with this drug for this condition in the public hospital setting; AND Patient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.	Code 15085
C15094	P15094	Cemiplimab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 7 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 15094
C15163	P15163	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment covering the first 6 treatment cycles Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15163

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must be initiated in combination with platinum-containing chemotherapy; AND The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.	
C15196	P15196	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather treatment Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND The treatment must be, at initiation of non-PBS-subsidised treatment with this drug, used in combination with platinum-containing chemotherapy; AND Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 15196
C15205	P15205	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma	Compliance with Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	Required procedures - Streamlined Authority Code 15205
C15455	P15455	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,875 mg administered once every 3 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition	Compliance with Authority Required procedures - Streamlined Authority Code 15455

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	
C15471	P15471	Nivolumab	Resectable non-small cell lung cancer (NSCLC) The condition must be at least one of: (i) node positive, (ii) at least 4 cm in size; AND The treatment must be for neoadjuvant use in a patient preparing for surgical resection; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with platinum-based chemotherapy. Patient must not be undergoing treatment with more than 3 PBS-subsidised doses of this drug per lifetime for this indication. In non-squamous type NSCLC where any of the following is known to be present, this drug must not be a PBS benefit: (i) activating epidermal growth factor receptor (EGFR) gene mutation, (ii) anaplastic lymphoma kinase (ALK) gene rearrangement.	Compliance with Authority Required procedures - Streamlined Authority Code 15471
C15485	P15485	Avelumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Initial treatment Patient must have received first-line platinum-based chemotherapy; AND Patient must not have progressive disease following first-line platinum-based chemotherapy; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 15485
C15500	P15500	Durvalumab	Unresectable Stage III non-small cell lung cancer Initial treatment Patient must have received platinum based chemoradiation therapy; AND The condition must not have progressed following platinum based chemoradiation therapy; AND Patient must have a WHO performance status of 0 or 1; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15500

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must be untreated with immunotherapy at commencement of this drug; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.	
C15527	P15527	Nivolumab	Urothelial carcinoma The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 120 days of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition; AND Patient must have received prior platinum containing neoadjuvant chemotherapy; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1. Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred. An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly.	Compliance with Authority Required procedures
C15818	P15818	Trastuzumab emtansine	Early HER2 positive breast cancer Initial adjuvant treatment The treatment must be prescribed within 12 weeks after surgery; AND Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery. The pathology report must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15819	P15819	Trastuzumab emtansine	Early HER2 positive breast cancer Continuing adjuvant treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures
C15820	P15820	Trastuzumab	Early HER2 positive breast cancer Initial treatment (3 weekly regimen)	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND	Code 15820
			The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND	
			Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR	
			Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.	
			HER2 positivity must be demonstrated by in situ hybridisation (ISH).	
			Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.	
			Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15826		Trastuzumab deruxtecan	Metastatic (Stage IV) HER2 positive breast cancer	Compliance with Authority Required procedures
			Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription; AND	
			The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; OR	
			The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy; AND	
			Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND	
			The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND	
			The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.	
			Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR	

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable). 2) Details of prior HER2 directed drug regimens prescribed for the patient. 3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable). Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15827	P15827	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one continuous course for this PBS indication. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures
C15828	P15828	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. The following information must be provided by the prescriber at the time of application: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH). (b) dates of treatment with trastuzumab and pertuzumab; (c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. All reports must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15831	P15831	Trastuzumab	Early HER2 positive breast cancer Initial treatment (weekly regimen)	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND	Code 15831
			The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND	
			Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR	
			Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.	
			HER2 positivity must be demonstrated by in situ hybridisation (ISH).	
			Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.	
			Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15832		Trastuzumab deruxtecan	Unresectable and/or metastatic HER2-low breast cancer	Compliance with Authority Required procedures
			Patient must have evidence of human epidermal growth factor receptor 2 (HER2)-low disease; AND	
			Patient must have received prior chemotherapy in the metastatic setting; OR	
			Patient must have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; AND	
			Patient must have received or be ineligible for endocrine therapy in the metastatic setting, if hormone receptor positive; AND	
			Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND	
			The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND	
			The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.	
			Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR	
			Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been	

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. HER2-low is defined as an immunohistochemical (IHC) score of 1+ or an IHC score of 2+ and a negative result on in situ hybridization (ISH). Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2-low status 2) Details of prior drug regimens prescribed for the patient 3) Cardiac function test results Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C16053	P16053	Avelumab	Stage IV (metastatic) Merkel Cell Carcinoma Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction; OR The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 16053
C16085	P16085	Avelumab	Stage IV (metastatic) Merkel Cell Carcinoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16085

Clause 1

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction; OR The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction.	
C16151	P16151	Nivolumab with relatlimab	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.	Compliance with Authority Required procedures - Streamlined Authority Code 16151
C16187	P16187	Daunorubicin with cytarabine	Acute Myeloid Leukaemia Induction therapy Patient must not have received prior chemotherapy as induction therapy for this condition; AND The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND The condition must not be either: (i) internal tandem duplication (ITD); (ii) tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3), mutation positive; AND Patient must not have favourable cytogenetic risk acute myeloid leukaemia (AML); AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must not exceed two cycles of induction therapy under this restriction. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The prescriber must confirm whether the patient has newly diagnosed therapy-related AML or AML-MRC. The test result and date of testing must be provided at the time of application and documented in the patient's file. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.	
C16188	P16188	Nivolumab with relatlimab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be uveal melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must weigh 40 kg or more; AND Patient must be at least 12 years of age. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four	Compliance with Authority Required procedures - Streamlined Authority Code 16188

Circumstances Code	Purposes Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			weeks under a flat dosing regimen. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.	
C16197	P16197	Daunorubicin with cytarabine	Acute Myeloid Leukaemia Consolidation therapy The treatment must be for consolidation treatment following induction treatment with this product; AND The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND The treatment must not exceed two cycles of consolidation therapy under this restriction. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.	Compliance with Authority Required procedures

Part 2—Variation rules

2 Variation rules

The following table sets out variation rules for variations codes, for the purposes of section 18.

Variation code	Listed Drug	Variation Rules
V4139	Granisetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5743	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5778	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024 (PB 31 of 2024)	27 Mar 2024 (F2024L00405)	1 Apr 2024 (s 2(1) item 1)	
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (May Update) Instrument 2024 (PB 44 of 2024)	30 Apr 2024 (F2024L00506)	1 May 2024 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (June Update) Instrument 2024 (PB 56 of 2024)	31 May 2024 (F2024L00612)	1 June 2024 (s 2(1) item 1)	—
National Health Legislation Amendment (Extension of Closing the Gap – PBS Co-payment Program) Instrument 2024 (PB 66 of 2024)	27 June 2024 (F2024L00803)	Sch 1 (items 12–28): 1 July 2024 (s 2(1) item 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (July Update) Instrument 2024 (PB 72 of 2024)	28 June 2024 (F2024L00828)	1 July 2024 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (August Update) Instrument 2024 (PB 80 of 2024)	31 July 2024 (F2024L00950)	1 Aug 2024 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (September Update) Instrument 2024 (PB 89 of 2024)	30 Aug 2024 (F2024L01099)	1 Sept 2024 (s 2(1) item 1)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (October Update) Instrument 2024 (PB 100 of 2024)	30 Sept 2024 (F2024L01244)	1 Oct 2024 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (November Update) Instrument 2024 (PB 116 of 2024)	31 Oct 2024 (F2024L01397)	1 Nov 2024 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (December Update) Instrument 2024 (PB 128 of 2024)	29 Nov 2024 (F2024L01543)	1 Dec 2024 (s 2(1) item 1)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 2	rep LA s 48D
s 5	am F2024L00803; F2024L00828; F2024L01543
Part 2	
Division 2	
s 14	am F2024L01543
s 14A	ad F2024L01543
s 21	am F2024L01543
Part 3	
Division 1	
s 26	am F2024L00803
Division 2	
s 27	am F2024L00803
s 28	am F2024L00803
Part 4	
s 36	am F2024L00803
s 37	am F2024L00803
s 39	am F2024L00803
Part 5	
Part 5	ad F2024L00803
s 40	ad F2024L00803
s 41	ad F2024L00803
Schedule 1	
Part 1	
c 1	am F2024L00506; F2024L00612; F2024L00828; F2024L00950; F2024L01099; F2024L01244; F2024L01397; F2024L01543
Part 2	
c 2	am F2024L00506; F2024L00612; F2024L00828; F2024L00950; F2024L01099; F2024L01244; F2024L01397; F2024L01543
Schedule 2	
c 1	am F2024L00506; F2024L00612 (Sch 1 items 9, 11 md not incorp); F2024L00828; F2024L00950; F2024L01099; F2024L01244
Schedule 3	
Part 1	
c 1	am F2024L00506; F2024L00612; F2024L00828; F2024L00950; F2024L01099; F2024L01244; F2024L01397; F2024L01543