



National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011

PB 79 of 2011

made under subsection 100(1) of the

National Health Act 1953

Compilation No. 137

Compilation date:	1 August 2023
Includes amendments up to:	F2023L01042
Registered:	14 August 2023

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 2011* that shows the text of the law as amended and in force on 1 August 2023 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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—General	1
Division 1—Preliminary	1
1 Name of Special Arrangement	1
3 Definitions.....	1
Division 2—Pharmaceutical benefits	5
4 Pharmaceutical benefits covered by this Special Arrangement	5
5 Application of Part VII of the Act.....	5
6 Responsible person.....	5
7 Authorised prescriber	6
8 Prescription circumstances	6
9 Maximum amount—chemotherapy drug	6
10 Maximum quantity—related pharmaceutical benefit.....	7
11 Maximum number of repeats—chemotherapy drug	7
12 Maximum number of repeats—related pharmaceutical benefit.....	8
13 Section 100 only supply	8
Part 2—Prescription	10
Division 1—Chemotherapy pharmaceutical benefits	10
14 Methods of prescribing chemotherapy pharmaceutical benefit	10
15 Information to be included in infusion prescription, other than chemotherapy medication chart prescription directing the supply of an infusion.....	10
16 Information to be included in chemotherapy medication chart prescription directing the supply of an infusion.....	11
17 Dose or number of repeats greater than maximum	11
18 Direction to vary dose of chemotherapy drug in infusion.....	12
Division 2—Related pharmaceutical benefits	14
19 Methods of prescribing related pharmaceutical benefit	14
20 Modified requirements for prescribing of related pharmaceutical benefits	14
Division 3—Authority required procedures	15
22 Authority required procedures to be followed	15
Part 3—Supply	18
30 Entitlement to infusion or related pharmaceutical benefit	18
31 Supply of infusion under this Special Arrangement	18
32 Supply of related pharmaceutical benefits under this Special Arrangement	18
33 Selection of chemotherapy pharmaceutical benefits to make infusion	18
34 Modified application of Act and Regulations	19
34A Conditions for approved pharmacists do not apply to infusions and certain related pharmaceutical benefits.....	20
Part 4—Claims, payment and provision of under co-payment data	21
Division 1—Claims for payment and provision of under co-payment data	21
36 How claims to be made	21
37 Modified references for claim and provision of under co-payment data	21
39 Modified requirements for supply of infusion	21

Division 2—Payment of claim	23
41 Payment of approved pharmacist or approved medical practitioner for supply of infusion	23
41A Paragraph 99(3)(b) of the Act does not apply to infusions and certain related pharmaceutical benefits.....	23
42 Payment of approved hospital authority or HSD hospital authority for supply of infusion	23
43 Payment of participating hospital authority for supply of related pharmaceutical benefit	23
45 Method of working out dispensed price.....	23
46 No separate entitlement to payment for supply of diluent	24
Division 2A—Payments to TGA licensed compounders	25
46A Payments in relation to infusions prepared between 1 July 2015 and 30 November 2017	25
46B Payments in relation to infusions prepared on or after 1 December 2017	25
Division 3—Dispensed price of chemotherapy drug	26
47 Dispensed price if drug is in infusion supplied by approved pharmacist or approved medical practitioner	26
48 Mark-up for a chemotherapy pharmaceutical benefit that does not have trastuzumab	27
49 Mark-up for chemotherapy pharmaceutical benefit that has trastuzumab	27
50 Dispensed price if drug is in infusion supplied by approved private hospital authority	28
51 Dispensed price if drug is in infusion supplied by public hospital authority.....	29
Division 4—Dispensed price of related pharmaceutical benefit	30
52 Dispensed price for supply of related pharmaceutical benefit	30
53 Quantity less than manufacturer’s pack	30
Part 5—Patient contributions	31
54 Supply of infusion by approved pharmacist or approved medical practitioner	31
55 Supply of infusion by approved hospital authority or HSD hospital authority.....	31
57 Supply of related pharmaceutical benefit by participating hospital authority	32
58 Special patient contribution for Schedule 5 pharmaceutical benefit.....	32
59 Amounts taken into account for eligibility for concession and entitlement cards	33
Part 5A – Record keeping	34
59A Keeping documents - chemotherapy medication chart prescriptions.....	34
Part 6—Transitional	35
60 Transitional provisions for existing medication chart prescribing.....	35
Schedule 1—Chemotherapy pharmaceutical benefits and chemotherapy drugs	36
Part 1—Chemotherapy pharmaceutical benefits and related information	36
Part 2—Chemotherapy drugs and related information	51
Schedule 2—Related pharmaceutical benefits	56
Schedule 3—Responsible Person Codes	63

Schedule 4—Circumstances and Purposes Codes	65
Schedule 5—Patient contributions	138
Endnotes	139
Endnote 1—About the endnotes	139
Endnote 2—Abbreviation key	140
Endnote 3—Legislation history	141
Endnote 4—Amendment history	149

Part 1—General

Division 1—Preliminary

1 Name of Special Arrangement

- (1) This Special Arrangement is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*.
- (2) This Special Arrangement may also be cited as PB 79 of 2011.

3 Definitions

- (1) In this Special Arrangement:

ABN has the same meaning as in the *A New Tax System (Australian Business Number) Act 1999*.

Act means the *National Health Act 1953*.

additional TGA licensed compounding fee, for the compounding of a dose of a chemotherapy drug for an infusion by a TGA licensed compounder – an amount of \$20.

authorised prescriber means:

- (a) for a chemotherapy pharmaceutical benefit—a kind of person identified by a prescriber code mentioned in the column in Part 1 of Schedule 1 headed ‘Authorised Prescriber’ for the benefit; or
- (b) for a related pharmaceutical benefit—a kind of person identified by a prescriber code mentioned in the column in Schedule 2 headed ‘Authorised Prescriber’ for the benefit.

authority prescription means a prescription that has been authorised:

- (a) in accordance with section 30 of the Regulations as modified by this Special Arrangement; or
- (b) in accordance with Division 3 of Part 2 of this Special Arrangement.

benefit card means any of the following:

- (a) a PBS Entitlement Card;
- (b) a PBS Safety Net Concession Card;
- (c) a Pensioner Concession Card;
- (d) a Health Care Card (including Low Income Health Care Card and Foster Child Health Care Card);
- (e) a Commonwealth Seniors Health Card;
- (f) a cleft lip and cleft palate identification card;
- (g) a DVA Gold Card;

Section 3

- (h) a DVA White Card;
- (i) a DVA Orange Card;
- (j) War Widow/Widower Transport Card;
- (k) a card or voucher approved by the Chief Executive Medicare for this paragraph.

chemotherapy drug, means a drug that is mentioned in the column in Part 1 of Schedule 1 headed 'Listed Drug' for one or more chemotherapy pharmaceutical benefits.

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

chemotherapy medication chart prescription means a section of medication chart directing the supply of an infusion or a related pharmaceutical benefit.

chemotherapy pharmaceutical benefit means a pharmaceutical benefit that is mentioned in Part 1 of Schedule 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 an infusion, so the infusion may be supplied by an approved supplier under this Special Arrangement.

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: Australian Healthcare Associates Pty Ltd is currently the Chemotherapy Compounding Payment Scheme Administration Agency.

diluent fee means an amount of \$5.77.

dispensing fee means an amount of \$8.37.

distribution fee means an amount of \$29.15.

dose, for a chemotherapy drug, means the quantity of the drug contained in an infusion, including unit of use, such as international units, grams, micrograms, or milligrams.

electronic chemotherapy medication chart prescription means a chemotherapy medication chart directing the supply of an infusion or a related pharmaceutical benefit, prepared in an electronic medication chart system.

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

eligible patient means a person who:

- (a) is, or is to be treated as, an eligible person within the meaning of the *Health Insurance Act 1973*; and

(b) is receiving treatment from an authorised prescriber.

eligible private hospital patient means an eligible patient who is receiving treatment at or from a private hospital.

eligible public hospital patient means an eligible patient who is receiving treatment at, or from, a public hospital as a non-admitted patient, day admitted patient or patient on discharge.

entitlement number, for an eligible patient, means the number listed on the patient's benefit card.

HSD hospital authority means a public hospital authority approved under section 10 of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*.

Human Services Department means the Department administered by the Human Services Minister.

infusion means a single treatment for a patient that is made from one or more chemotherapy pharmaceutical benefits.

infusion prescription means a prescription directing the supply of an infusion.

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

other Special Arrangement means another Special Arrangement under section 100 of the Act.

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

preparation fee means an amount of \$88.62.

Note: The preparation fee includes \$40 for compounding the dose of chemotherapy drug in the infusion, which is not indexed annually. Where a TGA licensed compounder has compounded the dose of a chemotherapy drug, an additional TGA licensed compounding fee of \$20 is payable to that TGA licensed compounder - see section 46B.

prescriber code means any of the following codes identifying the kind of person mentioned for the code:

- (a) MP—medical practitioner;
- (b) PDP—participating dental practitioner;
- (c) AO—authorised optometrist;
- (d) MW—authorised midwife;
- (e) NP—authorised nurse practitioner.

purposes code means the letter 'P' followed by a number.

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

Section 3

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

residential care service has the meaning given by the Regulations.

supplier means a person who may supply an infusion or related pharmaceutical benefit under Part 3 of this Special Arrangement.

TGA licensed compounder means a compounder who holds a license issued under the *Therapeutic Goods Act 1989* for aseptic compounding of sterile cytotoxic preparations.

under co-payment data means information in relation to the supply under this Special Arrangement of:

- (a) an infusion by an approved pharmacist, approved medical practitioner, approved hospital authority, or HSD hospital authority; or
- (b) a related pharmaceutical benefit by a participating hospital authority;

where a claim is not payable as the dispensed price for the supply under this Special Arrangement does not exceed the amount that the supplier was entitled to charge under subsection 54(2) or 55(2) for supply of an infusion, or under subsection 57(2) for supply of a related pharmaceutical benefit.

Note: Terms used in this Special Arrangement have the same meaning as in the Act—see section 13 of the *Legislative Instruments Act 2003*. These terms include:

- approved hospital authority
- approved medical practitioner
- approved pharmacist
- approved supplier
- pharmaceutical benefit
- pharmaceutical item
- public hospital authority.

- (2) Subject to a contrary intention, in this Special Arrangement, a reference to a chemotherapy medication chart prescription includes a reference to an electronic chemotherapy medication chart prescription.

Division 2—Pharmaceutical benefits

4 Pharmaceutical benefits covered by this Special Arrangement

- (1) This Special Arrangement applies to each pharmaceutical benefit mentioned in Part 1 of Schedule 1 or in Schedule 2.
- (2) Each pharmaceutical benefit to which this Special Arrangement applies is a brand of a listed drug mentioned in Part 1 of Schedule 1 or in Schedule 2:
 - (a) in the form mentioned in Part 1 of Schedule 1 or in Schedule 2 for the listed drug; and
 - (b) with the manner of administration mentioned in Part 1 of Schedule 1 or in Schedule 2 for the form of the listed drug.

Note: Each listed drug mentioned in Part 1 of Schedule 1 or in Schedule 2 has been declared by the Minister under subsection 85(2) of the Act. The form, manner of administration and brand mentioned in Part 1 of Schedule 1 or in Schedule 2 have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

5 Application of Part VII of the Act

- (1) Each pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act.
- (2) A provision of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act, applies subject to this Special Arrangement.

Note: Under this Special Arrangement, pharmaceutical benefits listed in Part 1 of Schedule 1 are supplied as an infusion made from one or more pharmaceutical benefits.

Note: See subsection 100(3) of the Act.

6 Responsible person

- (1) If a code is mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Responsible Person' for a brand of a pharmaceutical item, the person mentioned in paragraph (2)(a) is the responsible person for the brand of the pharmaceutical item.
- (2) For subsection (1):
 - (a) the person is the person mentioned in Schedule 3 for the code, with the ABN, if any, mentioned in Schedule 3 for the person; and
 - (b) the pharmaceutical item is the listed drug mentioned in Part 1 of Schedule 1 or in Schedule 2:
 - (i) in the form mentioned in Part 1 of Schedule 1 or in Schedule 2 for the listed drug; and
 - (ii) with the manner of administration mentioned in Part 1 of Schedule 1 or in Schedule 2 for the form of the listed drug.

Note: A person identified by a code in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Responsible Person' has been determined by the Minister, under section 84AF of the Act, to be the responsible person for the brand of the pharmaceutical item.

Section 7

7 Authorised prescriber

- (1) Only an authorised prescriber for a chemotherapy pharmaceutical benefit may prescribe the supply of an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit to an eligible patient.
- (2) Only an authorised prescriber for a related pharmaceutical benefit may prescribe the supply of the related pharmaceutical benefit to an eligible patient.

Note: Each person mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Authorised Prescriber' is authorised by subsection 88(1) of the Act, or has been authorised by the Minister under section 88 of the Act, to prescribe the pharmaceutical benefit unless the pharmaceutical benefit is mentioned in Part 2 of Schedule 1 to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)* (ready-prepared pharmaceutical benefits for supply only).

8 Prescription circumstances

- (1) If at least one circumstances code is mentioned in the column in Part 1 of Schedule 1 headed 'Circumstances' for a chemotherapy pharmaceutical benefit, the circumstances in Schedule 4 for a code are circumstances in which the supply of an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit may be prescribed.
- (2) If each chemotherapy pharmaceutical benefit that has the same chemotherapy drug has at least one circumstances code, then the supply of an infusion that includes the chemotherapy drug may only be prescribed in circumstances mentioned for a circumstances code.
- (3) If at least one circumstances code is mentioned in the column in Schedule 2 headed 'Circumstances' for a related pharmaceutical benefit:
 - (a) the circumstances mentioned in Schedule 4 for a code are circumstances in which the related pharmaceutical benefit may be prescribed; and
 - (b) the related pharmaceutical benefit may only be prescribed in circumstances mentioned for a circumstances code.

Note: Circumstances for a code mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Circumstances' have been determined by the Minister under paragraph 85(7)(b) of the Act, except for circumstances in relation to chemotherapy pharmaceutical benefits containing trastuzumab or fluorouracil.

9 Maximum amount—chemotherapy drug

- (1) This section applies subject to section 17.
- (2) The maximum amount of a chemotherapy drug that an authorised prescriber may direct to be included in an infusion in one infusion prescription or chemotherapy medication chart prescription is the amount mentioned in the column in Part 2 of Schedule 1 headed 'Maximum Amount' for the chemotherapy drug.
- (3) If at least one purposes code is mentioned in the column in Part 2 of Schedule 1 headed 'Purposes' for a chemotherapy drug, the amount mentioned in the

column headed 'Maximum Amount' is the maximum for the particular purposes mentioned in Schedule 4 for each code.

- (4) If no purposes code is mentioned in the column in Part 2 of Schedule 1 headed 'Purposes', the amount mentioned in the column headed 'Maximum Amount' is the maximum for all purposes, other than a purpose for which a different maximum is mentioned for the same chemotherapy drug.

10 Maximum quantity—related pharmaceutical benefit

- (2) The maximum quantity or number of units of the pharmaceutical item in a related pharmaceutical benefit that an authorised prescriber may direct to be supplied in one prescription is the quantity or number of units mentioned in the column in Schedule 2 headed 'Maximum Quantity' for the pharmaceutical benefit.
- (3) If at least one purposes code is mentioned in the column in Schedule 2 headed 'Purposes' for a related pharmaceutical benefit, the quantity or number of units mentioned in the column headed 'Maximum Quantity' is the maximum for the particular purposes mentioned in Schedule 4 for each code.
- (4) If no purposes code is mentioned in the column in Schedule 2 headed 'Purposes', the quantity or number of units mentioned in the column headed 'Maximum Quantity' is the maximum for all purposes, other than a purpose for which a different maximum is mentioned for the same related pharmaceutical benefit.
- (5) For subsection (2), the pharmaceutical item is the listed drug mentioned in Schedule 2:
- (a) in the form mentioned in Schedule 2 for the listed drug; and
 - (b) with the manner of administration mentioned in Schedule 2 for the form of the listed drug.

Note: The maximum quantities and numbers of units mentioned in the column in Schedule 2 headed 'Maximum quantity' have been determined by the Minister under paragraph 85A(2)(a) of the Act.

11 Maximum number of repeats—chemotherapy drug

- (1) This section applies subject to section 17.
- (2) The maximum number of occasions an authorised prescriber may, in one infusion prescription or chemotherapy medication chart prescription, direct that the supply of an infusion containing a chemotherapy drug be repeated is the number in the column in Part 2 of Schedule 1 headed 'Number of Repeats' for the chemotherapy drug.
- (3) If at least one purposes code is mentioned in the column in Part 2 of Schedule 1 headed 'Purposes' for the chemotherapy drug, the number of repeats mentioned in the column headed 'Number of Repeats' is the maximum number for the particular purposes mentioned in Schedule 4 for each code.

Section 12

- (4) If no purposes code is mentioned in the column in Part 2 of Schedule 1 headed ‘Purposes’, the number of repeats mentioned in the column headed ‘Number of Repeats’ is the maximum number for all purposes, other than a purpose for which a different maximum is mentioned for the same chemotherapy drug.
- (5) If an infusion contains more than one chemotherapy drug, the maximum number of repeats for the infusion is the smallest maximum number that applies in relation to one of the chemotherapy drugs.

12 Maximum number of repeats—related pharmaceutical benefit

- (2) The maximum number of occasions an authorised prescriber may, in one prescription, direct that the supply of a related pharmaceutical benefit be repeated is the number in the column in Schedule 2 headed ‘Number of Repeats’ for the related pharmaceutical benefit.
- (3) If at least one purposes code is mentioned in the column in Schedule 2 headed ‘Purposes’ for the related pharmaceutical benefit, the number of repeats mentioned in the column headed ‘Number of Repeats’ is the maximum number for the particular purposes mentioned in Schedule 4 for each code.
- (4) If no purposes code is mentioned in the column in Schedule 2 headed ‘Purposes’, the number of repeats mentioned in the column headed ‘Number of Repeats’ is the maximum number for all purposes, other than a purpose for which a different maximum is mentioned for the same related pharmaceutical benefit.

Note: The numbers of repeats mentioned in the column in Schedule 2 headed ‘Number of Repeats’ have been determined by the Minister under paragraph 85A(2)(b) of the Act.

13 Section 100 only supply

- (1) If the letter ‘D’ is mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed ‘Section 100 only’ for a listed drug, the listed drug may be supplied only in accordance with this Special Arrangement and any other Special Arrangement relating to the listed drug.

- (2) A pharmaceutical benefit that has a drug mentioned in subsection (1) is not available for general supply on the Pharmaceutical Benefits Scheme.

Note: The Minister has declared, under subsection 85(2A) of the Act, that the listed drug can only be supplied under a section 100 Special Arrangement.

- (3) If the letters ‘PB’ are mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed ‘Section 100 only’ for a pharmaceutical benefit, the pharmaceutical benefit may be supplied only in accordance with this Special Arrangement and any other Special Arrangement relating to the pharmaceutical benefit.

- (4) A pharmaceutical benefit mentioned in subsection (3) is not available for general supply on the Pharmaceutical Benefits Scheme.

Note: The Minister has determined, under paragraph 85(8)(a) of the Act, that this pharmaceutical benefit can only be supplied under a section 100 Special Arrangement.

- (5) If the letter 'C' is mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Section 100 only' for a pharmaceutical benefit and a code is mentioned in the column headed 'Circumstances', the pharmaceutical benefit may be supplied in the circumstances signified by the code only in accordance with this Special Arrangement and any other Special Arrangement relating to the pharmaceutical benefit.
- (6) A pharmaceutical benefit mentioned in subsection (5) is not available in the circumstances mentioned in subsection (5) for general supply on the Pharmaceutical Benefits Scheme.

Note: The Minister has determined, under paragraph 85(8)(b) of the Act, that one or more of the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written are circumstances in which the benefit can only be supplied under a section 100 Special Arrangement.

Part 2—Prescription

Division 1—Chemotherapy pharmaceutical benefits

14 Methods of prescribing chemotherapy pharmaceutical benefit

- (1) An authorised prescriber may prescribe a chemotherapy pharmaceutical benefit under this Special Arrangement by:
 - (a) writing an infusion prescription for an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit, in accordance with section 40 of the Regulations as modified by section 15 of this Special Arrangement; or
 - (b) preparing a chemotherapy medication chart prescription for an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit, in accordance with section 41 of the Regulations as modified by section 16 of this Special Arrangement.
- (2) However, a chemotherapy medication chart prescription directing the supply of an infusion may only be prepared for an eligible public hospital patient or eligible private hospital patient.
- (4) Where an infusion prescription is written in accordance with section 40 of the Regulations as modified by section 15, the prescription is taken to be written in accordance with section 40 of the Regulations.
- (4A) Where a chemotherapy medication chart prescription is written in accordance with section 41 of the Regulations as modified by section 16, the prescription is taken to be written in accordance with section 41 of the Regulations and Parts 4 and 5 of the Regulations apply as if a reference to a medication chart prescription included a reference to a chemotherapy medication chart prescription.
- (5) Paragraph 40(3)(a) of the Regulations does not apply to an infusion prescription.

Note: Section 41 of the Regulations does not prohibit same day prescribing for chemotherapy medication chart prescriptions.

15 Information to be included in infusion prescription, other than chemotherapy medication chart prescription directing the supply of an infusion

- (1) For paragraph 14(1)(a), this section modifies the requirements of section 40 of the Regulations.
- (2) An infusion prescription must include the following information:
 - (a) the name of each chemotherapy drug included in the infusion;
 - (b) the dose of each chemotherapy drug;
 - (c) if supply of the infusion is to be repeated—the number of times it is to be repeated.
- (3) An infusion prescription does not need to include the following information:

- (a) the form of a chemotherapy drug to be supplied;
- (b) the quantity or number of units of a pharmaceutical benefit to be supplied;
- (c) the number of times supply of a pharmaceutical benefit is to be repeated.

Note: If the prescription does include this information, a supplier is not required to follow the prescriber's directions—see section 33.

16 Information to be included in chemotherapy medication chart prescription directing the supply of an infusion

- (1) For paragraph 14(1)(b), this section modifies the requirements of section 41 of the Regulations.
- (2) A medication chart used to write a chemotherapy medication chart prescription directing the supply of an infusion is not required to be in a form approved by the Secretary under section 41(5) of the Regulations.
- (3) A completed section of a chemotherapy medication chart prescription directing the supply of an infusion must include the following information:
 - (a) the name of each chemotherapy drug included in the infusion; and
 - (b) for each chemotherapy drug – the dose, the frequency of administration and the route of administration.
- (4) However, a completed section of a chemotherapy medication chart prescription directing the supply of an infusion does not need to include the form of the chemotherapy drug to be supplied.
- (5) Section 41 of the Regulations applies as if references to a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital.
- (6) For an electronic chemotherapy medication chart prescription:
 - (a) paragraph 41(2)(c) of the Regulations does not apply to the completion of a section of the chart; and
 - (b) the authorised prescriber must electronically approve the electronic chemotherapy medication chart prescription in the electronic medication chart system; and
 - (c) the section of the chemotherapy medication chart must include each authority approval number (if any) for the prescription.

Note: If the medication chart includes information about the form or brand of a chemotherapy drug to be supplied, or the quantity, number of units or number of repeats of a particular pharmaceutical benefit to be supplied, a supplier is not required to follow the prescriber's directions except if they relate to the method of administering the chemotherapy drug - see section 33.

17 Dose or number of repeats greater than maximum

- (1) If an authorised prescriber prescribes a dose of a chemotherapy drug that is greater than the maximum amount permitted under section 9, then:

Section 18

- (a) for an infusion prescription written in accordance with paragraph 14(1)(a);
or
- (b) for a chemotherapy medication chart prescription written in accordance with paragraph 14(1)(b),

the prescription must be authorised in accordance with the procedures set out in section 30 of the Regulations as modified by subsection (2).

- (2) A reference in section 30 of the Regulations to:
 - (a) a determination in force under paragraph 85A(2)(a) of the Act is to be read as a reference to the maximum amount of the chemotherapy drug as described in section 9;
 - (b) compliance with subsection 41(2) of the Regulations is to be read as a reference to subsection 41(2) as modified by section 16;
 - (c) a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital; and
 - (d) an electronic prescription is to be read as reference to an electronic chemotherapy medication chart.
- (3) If an authorised prescriber directs that the supply of an infusion be repeated more times than the maximum number of repeats permitted under section 11 for one or more of the chemotherapy drugs included in the infusion, then:
 - (a) for an infusion prescription written in accordance with paragraph 14(1)(a);
or
 - (b) for a chemotherapy medication chart prescription written in accordance with paragraph 14(1)(b),

the prescription must be authorised in accordance with the procedures set out in section 30 of the Regulations as modified by subsection (4).

- (4) A reference in section 30 of the Regulations to:
 - (a) a determination in force under paragraph 85A(2)(b) of the Act is to be read as a reference to the maximum number of repeats for a chemotherapy drug as described in section 11;
 - (b) compliance with subsection 41(2) of the Regulations is to be read as a reference to subsection 41(2) as modified by section 16;
 - (c) a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital; and
 - (d) an electronic prescription is to be read as reference to an electronic chemotherapy medication chart.

18 Direction to vary dose of chemotherapy drug in infusion

- (1) An authorised prescriber may direct a supplier to increase or decrease the dose of a chemotherapy drug in a prescribed infusion, without writing a new infusion prescription or chemotherapy medication chart prescription, if the new dose of the drug is between 90% and 110% of the dose that was originally prescribed.

- (2) A new dose directed under subsection (1) that is greater than the maximum amount for the chemotherapy drug does not require approval under section 17.
- (3) If a supplier receives a direction in accordance with subsection (1), the supplier must record on the infusion prescription or chemotherapy medication chart prescription:
 - (a) the name of the authorised prescriber who gave the direction; and
 - (b) the means by which the supplier was notified of the direction (for example, by phone or by fax); and
 - (c) the date and time the supplier was notified.

Division 2—Related pharmaceutical benefits

19 Methods of prescribing related pharmaceutical benefit

- (1) An authorised prescriber may prescribe a related pharmaceutical benefit under this Special Arrangement by:
 - (a) writing a prescription for the related pharmaceutical benefit in accordance with section 40 of the Regulations; or
 - (b) writing a chemotherapy medication chart prescription for the related pharmaceutical benefit in accordance with section 41 of the Regulations as modified by section 20.
- (2) Where a chemotherapy medication chart prescription is written in accordance with section 41 of the Regulations as modified by section 20, it is taken to be written in accordance with section 41 of the Regulations and Parts 4 and 5 of the Regulations apply as if a reference to a medication chart prescription includes a reference to a chemotherapy medication chart prescription.

Note: Related pharmaceutical benefits can only be supplied under this Special Arrangement by a participating hospital authority to an eligible public hospital patient - see section 32.

20 Modified requirements for prescribing of related pharmaceutical benefits

- (1) For paragraph 19(1)(b), this section modifies the requirements of section 41 of the Regulations.
- (2) A medication chart used to write a chemotherapy medication chart prescription directing the supply of a related pharmaceutical benefit is not required to be in a form approved by the Secretary under subsection 41(5) of the Regulations.
- (3) Section 41 of the Regulations applies as if references to a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital.
- (4) For an electronic chemotherapy medication chart prescription:
 - (a) paragraph 41(2)(c) of the Regulations does not apply to the completion of a section of the chart; and
 - (b) the authorised prescriber must electronically approve the electronic chemotherapy medication chart prescription in the electronic medication chart system; and
 - (c) the section of the chemotherapy medication chart must include each authority approval number (if any) for the prescription.

Division 3—Authority required procedures

22 Authority required procedures to be followed

- (1) This section applies to an infusion prescription or chemotherapy medication chart prescription used to direct the supply of an infusion if:
- (a) a circumstances code is mentioned in Part 1 of Schedule 1 for a chemotherapy pharmaceutical benefit that has a chemotherapy drug included in the infusion; and
 - (b) the supply of the infusion is prescribed in the circumstances mentioned in Schedule 4 for the code; and
 - (c) the circumstances include one of the following statements:
 - (i) Compliance with Authority Required procedures;
 - (ii) Compliance with Written Authority Required procedures;
 - (iii) Compliance with Telephone Authority Required procedures;
 - (iv) Compliance with Written or Telephone Authority Required procedures.

Note: If at least one circumstances code is mentioned in Part 1 of Schedule 1 for each chemotherapy pharmaceutical benefit that has the same chemotherapy drug, supply of an infusion containing the chemotherapy drug may only be prescribed in one of the circumstances to which a code relates—see subsections 8(1) and (2).

- (1A) If the circumstances mentioned in Schedule 4 include ‘Compliance with Telephone Authority Required procedures’ or ‘Compliance with Written or Telephone Authority Required procedures’ then treat as if the words used are ‘Compliance with Authority Required Procedures’.
- (2) This section applies to a prescription (including a chemotherapy medication chart prescription) for a related pharmaceutical benefit if:
- (a) a circumstances code is mentioned in Schedule 2 for the related pharmaceutical benefit; and
 - (b) the related pharmaceutical benefit is prescribed in the circumstances mentioned in Schedule 4 for the code; and
 - (c) the circumstances include one of the following statements:
 - (i) Compliance with Authority Required procedures;
 - (ii) Compliance with Written Authority Required procedures;
 - (iii) Compliance with Telephone Authority Required procedures;
 - (iv) Compliance with Written or Telephone Authority Required procedures.

Note: If at least one circumstances code is mentioned in Schedule 2, the related pharmaceutical benefit may only be prescribed in one of the circumstances to which the code relates—see subsection 8(3).

- (2A) If the circumstances mentioned in Schedule 4 include ‘Compliance with Telephone Authority Required procedures’ or ‘Compliance with Written or Telephone Authority Required procedures’ then treat as if the words used are ‘Compliance with Authority Required Procedures’.

Section 22

- (3) The authority required procedures set out in sections 11 to 15 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, with the modifications set out in this section, are to be followed.

Note: See section 14 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* for Streamlined Authority Code.

- (4) A reference to a medication chart prescription in sections 11 to 15 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* includes a reference to a chemotherapy medication chart prescription.
- (5) An electronic chemotherapy medication chart prescription directing the supply of a written authority required pharmaceutical benefit may be authorised as set out in subsections (6) to (10).

Written authority required procedures - submission of electronic chemotherapy medication chart prescription

- (6) The authorised prescriber may submit to the Chief Executive Medicare:
- (a) a copy of the electronic chemotherapy medication chart prescription; or
 - (b) details of the prescription, by means of electronic communication to obtain an electronic authority, in accordance with subsection (7).

Note: For an authority required prescription for a pharmaceutical benefit that is not a written authority required pharmaceutical benefit, the prescription may be submitted in accordance with the procedures set out in paragraph 12(1)(a), (b), (c) or (d), as appropriate, of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*.

- (7) The details of the prescription submitted in accordance with paragraph (6)(b) must:
- (a) be given to the Chief Executive Medicare in writing; and
 - (b) be given by means of an electronic communication; and
 - (c) encrypted when given to the Chief Executive Medicare; and
 - (d) be given in accordance with any other requirements that would need to be met in order for the requirements to give the information in writing to be taken to have been met under the *Electronic Transactions Act 1999*.

Written authority required procedures - authorisation of electronic chemotherapy medication chart prescription

- (8) An electronic chemotherapy medication chart prescription submitted in accordance with paragraph (6)(a) may be authorised by the Chief Executive Medicare signing his or her authorisation on the copy of the prescription, and:
- (a) if the Chief Executive Medicare requires the authorised prescriber to alter the prescription — indicating this on the copy; and
 - (b) returning the copy to the authorised prescriber for alteration; and
 - (c) the authorised prescriber must enter the authorisation number into the electronic chemotherapy medication chart prescription.
- (9) An electronic chemotherapy medication chart prescription submitted in accordance with paragraph (6)(b) may be authorised by the Chief Executive Medicare sending his or her authorisation, by electronic communication,

including computer automated electronic communication, to the authorised prescriber.

- (10) If the Chief Executive Medicare authorises a prescription under subsection (9):
- (a) the Chief Executive Medicare must tell the authorised prescriber, by telephone or electronic communication, the approval number that has been allotted to the electronic chemotherapy medication chart prescription; and
 - (b) the authorised prescriber must enter that number into the electronic chemotherapy medication chart prescription.

Part 3—Supply

30 Entitlement to infusion or related pharmaceutical benefit

An eligible patient is entitled to receive an infusion or a related pharmaceutical benefit under this Special Arrangement without payment or other consideration, other than a charge made under Part 5.

31 Supply of infusion under this Special Arrangement

- (1) An infusion may be supplied under this Special Arrangement by any of the following:
 - (a) an approved pharmacist;
 - (b) an approved medical practitioner;
 - (c) an approved hospital authority for a private hospital; or
 - (d) a public hospital authority to an eligible public hospital patient.
- (2) However, a public hospital authority that is not a participating hospital authority may only supply an infusion that contains trastuzumab and that does not contain any other chemotherapy drug.
- (3) However, an infusion directed to be supplied under a chemotherapy medication chart prescription cannot be supplied by:
 - (a) an approved medical practitioner; or
 - (b) a public hospital authority that is not a participating hospital authority.

32 Supply of related pharmaceutical benefits under this Special Arrangement

A related pharmaceutical benefit may be supplied under this Special Arrangement by a participating hospital authority to an eligible public hospital patient.

33 Selection of chemotherapy pharmaceutical benefits to make infusion

Form, brand and method of administering

- (1) If an authorised prescriber directs the supply of a form of a chemotherapy drug in an infusion prescription or chemotherapy medication chart prescription, the supplier of the infusion may use chemotherapy pharmaceutical benefits with the same chemotherapy drug but a different form to make the infusion.
- (2) If an authorised prescriber directs the supply of a listed brand of a chemotherapy drug in an infusion prescription or chemotherapy medication chart prescription, the supplier of the infusion may use chemotherapy pharmaceutical benefits with the same chemotherapy drug but a different listed brand to make the infusion.

- (3) If an authorised prescriber identifies a method of administering a chemotherapy drug in an infusion prescription or chemotherapy medication chart prescription, the supply of the infusion must be consistent with the method.
- (4) Subsection (3) applies regardless of whether the method identified by the authorised prescriber is also a manner of administration for one or more chemotherapy pharmaceutical benefits containing the chemotherapy drug.

Note: Authorised prescribers are required to identify each chemotherapy drug in an infusion and the dose of each drug. They are not required to identify a particular chemotherapy pharmaceutical benefit by including the form, manner of administration or brand.

Quantity and number of repeats

- (5) If an authorised prescriber directs the supply of a quantity or number of units of a particular chemotherapy pharmaceutical benefit, the supplier of the infusion may disregard the direction.
- (6) If an authorised prescriber directs how many times the supply of a particular chemotherapy pharmaceutical benefit is to be repeated, the supplier of the infusion may disregard the direction.

Note: Authorised prescribers are required to identify the dose of each chemotherapy drug and for an infusion prescription the number of times that supply of the infusion is to be repeated. They are not required to identify the quantity or number of units of a pharmaceutical benefit to be supplied, or the number of times supply of a pharmaceutical benefit is to be repeated.

Circumstances

- (7) If an infusion prescription or chemotherapy medication chart prescription has been authorised in circumstances mentioned in Schedule 4, the supplier must only use chemotherapy pharmaceutical benefits for which the circumstances code for those circumstances is mentioned in the column in Part 1 of Schedule 1 headed 'Circumstances'.

34 Modified application of Act and Regulations

- (1) A supply of an infusion under this Special Arrangement is not an early supply of a specified pharmaceutical benefit within the meaning of subsection 84AAA(1) of the Act.
- (2) Subsections 51(2) to (4) of the Regulations do not apply to the supply of an infusion under this Special Arrangement.
- Note: The effect of those subregulations is to restrict how soon a repeat supply may be made. There is no restriction on how soon a repeat supply of an infusion may be made under this Special Arrangement.
- (3) Subsections 45(2) to (7) of the Regulations apply as if a reference to a person receiving treatment in or at a hospital includes a reference to a person receiving treatment from a hospital.
- (3A) Section 49 of the Regulations does not apply in relation to the writing of an infusion prescription.

Section 34A

Note: Section 49 of the Regulations does not apply in relation to the writing of a chemotherapy medication chart prescription because of section 14.

- (3B) Section 53 of the Regulations does not apply to the supply of an infusion on the basis of an infusion prescription.

Note: Section 53 of the Regulations does not apply to supplies on the basis of a chemotherapy medication chart prescription because of section 14.

- (3C) For an electronic chemotherapy medication chart prescription:
- (a) paragraph 45(2)(c) of the Regulations does not apply;
 - (b) the approved supplier or public hospital authority must verify in the electronic chemotherapy medication chart prescription that the pharmaceutical benefit has been supplied and the date on which it was supplied; and
 - (c) for section 51 of the Regulations, a reference to writing "immediate supply necessary" on the prescription is taken to be a reference to including those words in the electronic chemotherapy medication chart prescription.
- (4) A reference elsewhere in the Regulations to the supply of a pharmaceutical benefit is taken to include the supply of an infusion under this Special Arrangement.

34A Conditions for approved pharmacists do not apply to infusions and certain related pharmaceutical benefits

The *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017* does not apply to the dispensing or supply of:

- (a) an infusion; or
 - (b) a pharmaceutical benefit mentioned in Schedule 2 for which the manner of administration is injection or intravesical;
- that is supplied under this Special Arrangement.

Part 4—Claims, payment and provision of under co-payment data

Division 1—Claims for payment and provision of under co-payment data

36 How claims to be made

- (1) The following may make a claim for payment for the supply of an infusion or related pharmaceutical benefit to an eligible patient under this Special Arrangement in accordance with section 99AAA of the Act, and the rules made under subsection 99AAA(8) of the Act, as modified by this Division:
 - (a) an approved supplier;
 - (b) an HSD hospital authority.

37 Modified references for claim and provision of under co-payment data

- (1) The rules made by the Minister under subsection 99AAA(8) and subsection 98AC(4) of the Act apply to a claim or provision of under co-payment data as follows:
 - (a) a reference to an approved supplier or an approved hospital authority includes a reference to an HSD hospital authority;
 - (ab) a reference to a medication chart prescription includes a reference to a chemotherapy medication chart prescription;
 - (b) a reference to a number allotted to an approval under section 16 of the Regulations includes a reference to a number allotted to an approval under section 10 of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* for a HSD hospital authority; and
 - (c) the definition of under co-payment data in section 4 of this Special Arrangement replaces the definition of under co-payment data appearing in the rules made under subsection 98AC(4) of the Act.

39 Modified requirements for supply of infusion

For a claim or provision of under co-payment data for supply of an infusion, the requirements in the rules made by the Minister under subsection 99AAA(8) and subsection 98AC(4) of the Act are modified as follows:

- (a) a reference to a pharmaceutical benefit includes a reference to an infusion;
- (b) a reference to an authority prescription in the rules includes a reference to an authority prescription within the meaning given by section 3 of this Special Arrangement;
- (c) the claim or provision of under co-payment data must include:
 - (i) a drug code for each chemotherapy drug in the infusion, being the code for the drug published in the *Schedule of Pharmaceutical Benefits* published by the Department; and

Part 4 Claims, payment and provision of under co-payment data

Division 1 Claims for payment and provision of under co-payment data

Section 39

- (ii) the dose of each chemotherapy drug in the infusion; and
- (iii) the compounder ID of the site at which the compounder compounded the dose of a chemotherapy drug for the infusion; and
- (d) the supplier is not required to include in the claim or provision of under co-payment data:
 - (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 applies; or
 - (iv) whether or not immediate supply was necessary.

Division 2—Payment of claim

41 Payment of approved pharmacist or approved medical practitioner for supply of infusion

An approved pharmacist or approved medical practitioner who makes a claim under Division 1 for the supply of an infusion is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of the infusion is greater than the amount that the approved pharmacist or approved medical practitioner was required to charge under subsection 54(2).

41A Paragraph 99(3)(b) of the Act does not apply to infusions and certain related pharmaceutical benefits

Paragraph 99(3)(b) of the Act does not apply to the supply of:

- (a) an infusion; or
- (b) a pharmaceutical benefit mentioned in Schedule 2 for which the manner of administration is injection or intravesical;

under this Special Arrangement.

42 Payment of approved hospital authority or HSD hospital authority for supply of infusion

An approved hospital authority or HSD hospital authority that makes a claim under Division 1 for the supply of an infusion is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of the infusion is greater than the amount that the approved hospital authority or HSD hospital authority was entitled to charge under subsection 55(2).

43 Payment of participating hospital authority for supply of related pharmaceutical benefit

A participating hospital authority that makes a claim under Division 1 for the supply of a related pharmaceutical benefit is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of the related pharmaceutical benefit is greater than the amount that the supplier was entitled to charge under subsection 57(2).

45 Method of working out dispensed price

Infusion

- (1) The dispensed price for the supply of an infusion is the sum of:
 - (a) the dispensed prices of the doses of chemotherapy drugs in the infusion;and

Section 46

- (b) if the supply is a repeated supply—an amount equivalent to the amount that may be charged under subsection 87(2) of the Act for the supply of a pharmaceutical benefit to the eligible patient.
- (2) The dispensed price for a dose of a chemotherapy drug is to be worked out under Division 3.

Related pharmaceutical benefit

- (3) The dispensed price for the supply of a related pharmaceutical benefit is to be worked out under Division 4.

Rounding

- (4) A dispensed price worked out under Division 3 or 4 is rounded to the nearest cent, with a half cent being rounded up.

46 No separate entitlement to payment for supply of diluent

- (1) If a supplier adds a pharmaceutical benefit to an infusion supplied under this Special Arrangement as a diluent, no amount is payable under Part VII of the Act for supply of the pharmaceutical benefit.
- (2) Subsection (1) applies regardless of whether the pharmaceutical benefit added as a diluent is one to which this Special Arrangement applies.

Note: For the application of this Special Arrangement to pharmaceutical benefits, see section 5.

Division 2A—Payments to TGA licensed compounders

46A Payments in relation to infusions prepared between 1 July 2015 and 30 November 2017

- (1) A TGA licensed compounder may make a claim for payment for the compounding of a dose of a chemotherapy drug for an infusion prepared between 1 July 2015 and 30 November 2017.
- (2) A claim under subsection (1) must:
 - (a) be in writing; and
 - (b) include a certification by the TGA licensed compounder that:
 - (i) each dose of a chemotherapy drug for the infusion to which the claim relates was prepared in accordance with a compounding order; and
 - (ii) the information provided in the claim is correct.
- (3) If a claim is made under subsection (1), the Secretary may, at his or her discretion, if the Secretary is satisfied on reasonable grounds that it is appropriate to do so, pay an amount of \$20 to the TGA licensed compounder for the compounding.

46B Payments in relation to infusions prepared on or after 1 December 2017

- (1) If a TGA licensed compounder compounds a dose of a chemotherapy drug for an infusion prepared on or after 1 December 2017, the compounder is entitled to be paid an additional TGA licensed compounding fee by the Commonwealth.
- (2) A TGA licensed compounder must not be paid more than one additional TGA licensed compounding fee for the compounding of a dose of a chemotherapy drug for a single infusion that is prepared in accordance with an infusion prescription for an individual patient.

Division 3—Dispensed price of chemotherapy drug

47 Dispensed price if drug is in infusion supplied by approved pharmacist or approved medical practitioner

- (1) For a dose of a chemotherapy drug in an infusion supplied by an approved pharmacist or an approved medical practitioner to an eligible patient, 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 of 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.

Note: A chemotherapy pharmaceutical benefit is in a form mentioned in Part 1 of Schedule 1 for a listed drug—see section 5. The form establishes the amount of the drug that is in a quantity of 1 of the chemotherapy pharmaceutical benefit.

- (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 ex-manufacturer price for a quantity of 1 of 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:
 - (i) if the chemotherapy pharmaceutical benefit does not have trastuzumab—section 48; or
 - (ii) if the chemotherapy pharmaceutical benefit has trastuzumab—section 49.

Note: The reference price and the ex-manufacturer price for a quantity of 1 are 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 a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price of the pack would be divided by 3 to obtain the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

48 Mark-up for a chemotherapy pharmaceutical benefit that does not have trastuzumab

For subparagraph 47(4)(b)(i), the mark-up for a chemotherapy pharmaceutical benefit that does not have trastuzumab is:

(mark-up for maximum multiple) ÷ (maximum multiple of pharmaceutical benefit).

where:

mark-up for maximum multiple means the administration, handling and infrastructure fee worked out under the determination made under paragraph 98B(1)(a) of the Act.

maximum multiple of pharmaceutical benefit is the whole number of multiples of the form of the chemotherapy pharmaceutical benefit required to obtain the maximum amount of the chemotherapy drug in the benefit that is permitted under section 9.

Note: The form of a chemotherapy pharmaceutical benefit is mentioned in Part 1 of Schedule 1 in the column headed 'Form'—see section 5.

49 Mark-up for chemotherapy pharmaceutical benefit that has trastuzumab

- (1) For subparagraph 47(4)(b)(ii), the mark-up for a chemotherapy pharmaceutical benefit that has trastuzumab is:

(mark-up for maximum multiple) ÷ (maximum multiple of pharmaceutical benefit)

where:

mark-up for maximum multiple means the amount worked out under subsection (2).

maximum multiple of pharmaceutical benefit is the whole number of multiples of the form of the chemotherapy pharmaceutical benefit required to obtain the maximum amount of trastuzumab that is permitted under section 9.

Note: The form of a chemotherapy pharmaceutical benefit is mentioned in Part 1 of Schedule 1 in the column headed 'Form'—see section 5.

- (2) The mark-up for the maximum multiple of a chemotherapy pharmaceutical benefit with an ex-manufacturer price mentioned in the table is the amount mentioned in the table.

Section 50

Item	Ex-manufacturer price for maximum multiple of pharmaceutical benefit	Mark-up for maximum multiple
1	≤ \$40	10% of ex-manufacturer price for maximum multiple of pharmaceutical benefit
2	> \$40, ≤ \$100	\$4
3	> \$100, ≤ \$1 000	4% of ex-manufacturer price for maximum multiple of pharmaceutical benefit
4	> \$1 000	\$40

50 Dispensed price if drug is in infusion supplied by approved private hospital authority

- (1) For a dose of a chemotherapy drug in an infusion supplied by an approved hospital authority of a private hospital to an eligible patient, 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 of 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.

Note: A chemotherapy pharmaceutical benefit is in a form mentioned in Part 1 of Schedule 1 for a listed drug—see section 5. The form establishes the amount of the drug that is in a quantity of 1 of the chemotherapy pharmaceutical benefit.

- (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 ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit, rounded to the nearest cent (with a half cent being rounded up); and

- (b) 1.4% of the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

Note: The reference price and the ex-manufacturer price for a quantity of 1 are 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 a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price of the pack would be divided by 3 to obtain the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

51 Dispensed price if drug is in infusion supplied by public hospital authority

- (1) For a dose of a chemotherapy drug in an infusion supplied by a public hospital authority to an eligible patient, 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 of 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.

Note: A chemotherapy pharmaceutical benefit is in a form mentioned in Part 1 of Schedule 1 for a listed drug—see section 5. The form establishes the amount of the drug that is in a quantity of 1 of the chemotherapy pharmaceutical benefit.

- (4) In this section, the *reference price* of a chemotherapy pharmaceutical benefit is the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit, rounded to the nearest cent (with a half cent being rounded up).

Note: The reference price and the ex-manufacturer price for a quantity of 1 are 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 a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price of the pack would be divided by 3 to obtain the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

Division 4—Dispensed price of related pharmaceutical benefit

52 Dispensed price for supply of related pharmaceutical benefit

- (1) For a related pharmaceutical benefit supplied by a participating hospital authority to an eligible public hospital patient, the *dispensed price* is as follows:
 - (a) if the quantity of the related pharmaceutical benefit that is ordered and supplied is equal to the quantity contained in the manufacturer's pack—the ex-manufacturer price for the pack;
 - (b) if the quantity of the related pharmaceutical benefit that is ordered and supplied is less than the quantity contained in the manufacturer's pack—the amount worked out under section 53;
 - (c) if the quantity of the related pharmaceutical benefit that is ordered and supplied is more than the quantity contained in the manufacturer's pack—the sum of:
 - (i) the ex-manufacturer price for each complete pack in the quantity; and
 - (ii) the amount worked out under section 53 for any remainder.
- (2) However, if there are 2 or more related pharmaceutical benefits that are different brands of the same pharmaceutical item, the dispensed price of those pharmaceutical benefits is to be based on the pharmaceutical benefit with the lowest ex-manufacturer price.

53 Quantity less than manufacturer's pack

For paragraph 52(1)(b) and subparagraph 52(1)(c)(ii), the amount for a quantity of a related pharmaceutical benefit that is less than the quantity contained in the manufacturer's pack (a *broken quantity*) is worked out by:

- (a) dividing the quantity or number of units in the broken quantity by the quantity or number of units in the manufacturer's pack expressed as a percentage to 2 decimal places; and
- (b) applying that percentage to the ex-manufacturer price for the complete pack.

Part 5—Patient contributions

54 Supply of infusion by approved pharmacist or approved medical practitioner

- (1) The amount that an approved pharmacist or approved medical practitioner may or must charge an eligible patient for the supply of an infusion is the total of the amounts set out in this section.

Patient co-payment for original supply

- (2) For an original supply of an infusion, the approved pharmacist or approved medical practitioner must charge the eligible patient an amount that is equivalent to the amount that is required to 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 infusion, not a separate amount for supply of each chemotherapy pharmaceutical benefit used to make the infusion.

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

Special patient contribution for Schedule 5 pharmaceutical benefit

- (4) If a chemotherapy pharmaceutical benefit the approved pharmacist or approved medical practitioner uses to make the infusion is mentioned in Schedule 5, the approved pharmacist or approved medical practitioner may charge the eligible patient an amount not exceeding the amount for the chemotherapy pharmaceutical benefit worked out under section 58.

Note: If more than one chemotherapy pharmaceutical benefit used to make an infusion is mentioned in Schedule 5, a separate amount may be charged for each one.

55 Supply of infusion by approved hospital authority or HSD hospital authority

- (1) The amount that an approved hospital authority or HSD hospital authority may charge an eligible patient for the supply of an infusion is the total of the amounts set out in this section.

Patient co-payment for original supply

- (2) For an original supply of an infusion, the hospital authority may charge the eligible 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 infusion, not a separate amount for supply of each chemotherapy pharmaceutical benefit used to make the infusion.

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

Section 57

Special patient contribution for Schedule 5 pharmaceutical benefit

- (4) If a chemotherapy pharmaceutical benefit the hospital authority uses to make the infusion is mentioned in Schedule 5, the hospital authority may charge the eligible patient an amount not exceeding the amount for the chemotherapy pharmaceutical benefit worked out under section 58.

Note: If more than one chemotherapy pharmaceutical benefit used to make an infusion is mentioned in Schedule 5, a separate amount may be charged for each one.

57 Supply of related pharmaceutical benefit by participating hospital authority

- (1) The amount that a participating hospital authority may charge an eligible public hospital patient for the supply of a related pharmaceutical benefit is the total of the amounts set out in this section.

Patient co-payment

- (2) The participating hospital authority may charge the eligible public hospital 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 the related pharmaceutical benefit from an approved pharmacist.

Special patient contribution for Schedule 5 pharmaceutical benefit

- (3) If the related pharmaceutical benefit is mentioned in Schedule 5, the participating hospital authority may also charge the eligible public hospital patient an amount not exceeding the amount for the related pharmaceutical benefit worked out under section 58.

58 Special patient contribution for Schedule 5 pharmaceutical benefit

- (1) The amount an eligible patient may be charged for a pharmaceutical benefit mentioned in Schedule 5 is worked out by subtracting the amount mentioned for the pharmaceutical benefit in the 'Approved Ex-manufacturer Price' column in Schedule 5 from the amount mentioned for the pharmaceutical benefit in the 'Claimed Ex-manufacturer Price' column in Schedule 5.
- (2) However, the amounts mentioned in the 'Approved Ex-manufacturer price' and 'Claimed Ex-manufacturer price' columns must be adjusted proportionally if:
 - (a) for a chemotherapy pharmaceutical benefit—the quantity or number of units of the pharmaceutical benefit used to make the infusion is more or less than the number mentioned in the 'Quantity or Number of Units' column; and
 - (b) for a related pharmaceutical benefit—the quantity or number of units of the pharmaceutical benefit supplied is more or less than the number mentioned in the 'Quantity or Number of Units' column.

59 Amounts taken into account for eligibility for concession and entitlement cards

An amount charged under any of the following provisions is to be taken into account when determining a person's eligibility for a concession card or entitlement card under section 84C of the Act:

- (a) subsection 54(2);
- (b) subsection 55(2);
- (d) subsection 57(2).

Part 5A – Record keeping

59A Keeping documents - chemotherapy medication chart prescriptions

- (1) If an approved supplier or public hospital authority supplies an infusion or a related pharmaceutical benefit under this Special Arrangement on the basis of a chemotherapy medication chart prescription, the supplier must keep the chemotherapy medication chart, or a copy of the chemotherapy medication chart, on which the supplier wrote:
 - (a) the details required by paragraph 45(2)(c) of the Regulations; or
 - (b) for an electronic chemotherapy medication chart - the verification required by subsection 34(3C) in relation to the prescription.
- (2) The chemotherapy medication chart or copy of the chemotherapy medication chart must be kept for a period of at least 2 years from the date the infusion or related pharmaceutical benefit is supplied by the approved supplier or public hospital authority.

Note 1: The chemotherapy medication chart, or a copy of the chemotherapy medication chart, may be kept in an electronic form (see subsection 12(2) of the *Electronic Transactions Act 1999*).

Note 2: Requirements to keep documents in relation to the supply of an infusion or a related pharmaceutical benefit on the basis of an infusion prescription are in section 59 of the Regulations.

Part 6—Transitional

60 Transitional provisions for existing medication chart prescribing

- (1) This section applies where, before the commencement time, an authorised prescriber has written an infusion medication chart prescription or a medication chart prescription directing the supply of a related pharmaceutical benefit, in accordance with this Special Arrangement as in force immediately before that time (a *relevant existing prescription*).
- (2) This Special Arrangement as in force immediately before commencement time continues to apply to:
 - (a) the prescribing of chemotherapy pharmaceutical benefits or related pharmaceutical benefits using the same chart used to write the relevant existing prescription, during the chart's period of validity under subsection 45(4) of the Regulations; and
 - (b) the supply of a chemotherapy pharmaceutical benefit or related pharmaceutical benefit made on the basis of that prescription and claims, payment and provisions of under co-payment data in relation to such a supply.
- (3) In this section:

commencement time means the commencement of the *National Health (Efficient Funding of Chemotherapy) Amendment (COVID-19 Simplified Prescribing) Special Arrangement 2020*.

infusion medication chart prescription has the meaning given by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* as in force immediately before the commencement time.

medication chart prescription has the meaning given by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* as in force immediately before the commencement time.

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Schedule 1—Chemotherapy pharmaceutical benefits and chemotherapy drugs

(sections 3, 4, 6, 8, 9, 11, 13, 22 and 33)

Part 1—Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Arsenic	Injection concentrate containing arsenic trioxide 10 mg in 10 mL	Injection	Arsenic Trioxide Accord	OC	MP	C4793 C5997 C6018	D
			Arsenic Trioxide-AFT	AE	MP	C4793 C5997 C6018	D
			Arsenic Trioxide Juno	JU	MP	C4793 C5997 C6018	D
			Phenasen	FF	MP	C4793 C5997 C6018	D
Atezolizumab	Solution concentrate for I.V. infusion 840 mg in 14 mL	Injection	Tecentriq	RO	MP	C10215 C10257 C10509 C10972 C13446 C13451	D
	Solution concentrate for I.V. infusion 1200 mg in 20 mL	Injection	Tecentriq	RO	MP	C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13442 C13443 C13448	D
Avelumab	Solution concentrate for I.V. infusion 200 mg in 10 mL	Injection	Bavencio	SG	MP	C8947 C10023 C13290 C13303 C13313	D
Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg	Injection	Bendamustine Sandoz	SZ	MP	C7943 C7944 C7972	D

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Bendamustine Viatrix	AF	MP	C7943 C7944 C7972	D
			Ribomustin	JC	MP	C7943 C7944 C7972	D
	Powder for injection containing bendamustine hydrochloride 100 mg	Injection	Bendamustine Sandoz	SZ	MP	C7943 C7944 C7972	D
			Bendamustine Viatrix	AF	MP	C7943 C7944 C7972	D
			Ribomustin	JC	MP	C7943 C7944 C7972	D
Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL	Injection	Abevmy	AF	MP		D
			Bevaciptin	LR	MP		D
			Mvasi	AN	MP		D
	Solution for I.V. infusion 400 mg in 16 mL	Injection	Abevmy	AF	MP		D
			Bevaciptin	LR	MP		D
			Mvasi	AN	MP		D
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	CIPLA BLEOMYCIN	LR	MP	C6224 C6275	D
			DBL Bleomycin Sulfate	PF	MP	C6224 C6275	D
Blinatumomab	Powder for I.V. infusion 38.5 micrograms	Injection	Blinicyto	AN	MP	C9369 C9519 C9911 C9936 C9937	D

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Bortezomib	Powder for injection 1 mg	Injection	Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib Juno	JU	MP	C11099 C13745	D
			DBL Bortezomib	PF	MP	C11099 C13745	D
			Velcade	JC	MP	C11099 C13745	D
	Powder for injection 2.5 mg	Injection	Bortezomib Juno	JU	MP	C11099 C13745	D
			DBL Bortezomib	PF	MP	C11099 C13745	D
	Powder for injection 3 mg	Injection	DBL Bortezomib	PF	MP	C11099 C13745	D
			Velcade	JC	MP	C11099 C13745	D
	Powder for injection 3.5 mg	Injection	Bortezom	CR	MP	C11099 C13745	D
			Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib-AFT	AE	MP	C11099 C13745	D
			Bortezomib Baxter	BX	MP	C11099 C13745	D
			Bortezomib Juno	JU	MP	C11099 C13745	D
			Bortezomib Sandoz	SZ	MP	C11099 C13745	D
			BORTEZOMIB-TEV A	TB	MP	C11099 C13745	D
			DBL Bortezomib	PF	MP	C11099 C13745	D
			Velcade	JC	MP	C11099 C13745	D
Solution for injection 2.5 mg in 1 mL	Injection	Bortezomib Accord	OC	MP	C11099 C13745	D	
		Bortezomib Ever	IT	MP	C11099 C13745	D	

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Pharma				
	Solution for injection 3.5 mg in 1.4 mL	Injection	Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib Ever Pharma	IT	MP	C11099 C13745	D
Brentuximab vedotin	Powder for I.V. infusion 50 mg	Injection	Adcetris	TK	MP	C13134 C13179 C13181 C13182 C13208 C13209 C13212 C13231 C13259 C13261	D
Cabazitaxel	Concentrated injection 60 mg in 1.5 mL, with diluent	Injection	Cabazitaxel Juno	JU	MP	C13207	D
			MSN Cabazitaxel	RQ	MP	C13207	D
	Solution concentrate for I.V. infusion 60 mg in 3 mL	Injection	Cabazitaxel Accord	OC	MP	C13207	D
	Solution concentrate for I.V. infusion 60 mg in 6 mL	Injection	Cabazitaxel Ever Pharma	IT	MP	C13207	D
Carboplatin	Solution for I.V. injection 450 mg in 45 mL	Injection	Carboplatin Accord	OC	MP		D
			DBL Carboplatin	PF	MP		D
Carfilzomib	Powder for injection 10 mg	Injection	Kyprolis	AN	MP	C12694 C12849 C12930 C12934	D
	Powder for injection 30 mg	Injection	Kyprolis	AN	MP	C12694 C12849 C12930 C12934	D
	Powder for injection 60 mg	Injection	Kyprolis	AN	MP	C12694 C12849 C12930 C12934	D
Cemiplimab	Solution concentrate for I.V. infusion 350 mg in	Injection	Libtayo	SW	MP	C13322 C13373	D

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	7 mL					C13411 C13419 C13766	
Cetuximab	Solution for I.V. infusion 100 mg in 20 mL	Injection	Erbitux	SG	MP	C4785 C4788 C4794 C4908 C4912 C12016 C12045 C12470 C12483	D
	Solution for I.V. infusion 500 mg in 100 mL	Injection	Erbitux	SG	MP	C4785 C4788 C4794 C4908 C4912 C12016 C12045 C12470 C12483	D
Cisplatin	I.V. injection 50 mg in 50 mL	Injection	Cisplatin Accord	OC	MP		D
	I.V. injection 100 mg in 100 mL	Injection	Cisplatin Accord	OC	MP		D
Cladribine	Injection 10 mg in 5 mL	Injection	Litak	AF	MP	C6265	D
	Solution for I.V. infusion 10 mg in 10 mL single use vial	Injection	Leustatin	IX	MP	C6265	D
Cyclophosphamide	Powder for injection 500 mg (anhydrous)	Injection	Endoxan	BX	MP		PB
	Powder for injection 1 g (anhydrous)	Injection	Endoxan	BX	MP		PB
	Powder for injection 2 g (anhydrous)	Injection	Endoxan	BX	MP		PB
Cytarabine	Injection 100 mg in 5 mL vial	Injection	Pfizer Australia Pty Ltd	PF	MP		D
Daratumumab	Solution concentrate for I.V. infusion 100 mg in 5 mL	Injection	Darzalex	JC	MP	C12691 C12844 C12845 C13752	PB
	Solution concentrate for I.V. infusion 400 mg in 20 mL	Injection	Darzalex	JC	MP	C12691 C12844 C12845 C13752	PB

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Docetaxel	Solution concentrate for I.V. infusion 80 mg in 4 mL	Injection	Docetaxel Accord	OC	MP		D
	Solution concentrate for I.V. infusion 80 mg in 8 mL	Injection	DBL Docetaxel Concentrated Injection	PF	MP		D
	Solution concentrate for I.V. infusion 160 mg in 8 mL	Injection	Docetaxel Accord	OC	MP		D
	Solution concentrate for I.V. infusion 160 mg in 16 mL	Injection	DBL Docetaxel Concentrated Injection	PF	MP		D
Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 50 mg in 25 mL single dose vial	Injection/ intravesical	Adriamycin	PF	MP		D
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial	Injection/ intravesical	Adriamycin	PF	MP		D
			Doxorubicin ACC	OC	MP		D
Doxorubicin - pegylated liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	BX	MP		D
			Liposomal Doxorubicin SUN	RA	MP		D
	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 50 mg in 25 mL	Injection	Caelyx	BX	MP		D
			Liposomal	RA	MP		D

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Doxorubicin SUN				
Durvalumab	Solution concentrate for I.V. infusion 120 mg in 2.4 mL	Injection	Imfinzi	AP	MP	C10126 C12271	D
	Solution concentrate for I.V. infusion 500 mg in 10 mL	Injection	Imfinzi	AP	MP	C10126 C12271	D
Elotuzumab	Powder for injection 300 mg	Injection	Empliciti	BQ	MP	C12847 C12891	D
	Powder for injection 400 mg	Injection	Empliciti	BQ	MP	C12847 C12891	D
Epirubicin	Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL	Injection/ intravesical	Epirubicin Accord	OC	MP		D
Eribulin	Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL	Injection	Halaven	EI	MP	C4649 C7258 C7280	D
Etoposide	Powder for I.V. infusion 1 g (as phosphate)	Injection	Etopophos	LM	MP		PB
	Solution for I.V. infusion 100 mg in 5 mL	Injection	Etoposide Ebewe	SZ	MP		PB
Fludarabine	Powder for I.V. injection containing fludarabine phosphate 50 mg	Injection	Fludarabine Juno	JO	MP		PB
	Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL	Injection	Fludarabine Ebewe	SZ	MP		PB
Fluorouracil	Injection 500 mg in 10 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297	D
	Injection 1000 mg in 20 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297	D
			Fluorouracil Ebewe	SZ	MP	C6266 C6297	D
	Injection 2500 mg in 50 mL	Injection	DBL Fluorouracil Injection BP	PF	MP	C6266 C6297	D
			Fluorouracil Accord	OC	MP	C6266 C6297	D

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Gemcitabine	Injection 5000 mg in 100 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297	D
			Fluorouracil Ebewe	SZ	MP	C6266 C6297	D
	Solution for injection 1 g (as hydrochloride) in 26.3 mL	Injection	DBL Gemcitabine Injection	PF	MP		D
	Solution for injection 2 g (as hydrochloride) in 52.6 mL		DBL Gemcitabine Injection	PF	MP		D
Gemtuzumab ozogamicin	Powder for injection 5 mg	Injection	Mylotarg	PF	MP	C12559 C12566	D
Idarubicin	Solution for I.V. injection containing idarubicin hydrochloride 5 mg in 5 mL	Injection	Zavedos Solution	PF	MP	C6247	PB
Ifosfamide	Powder for I.V. injection 1 g	Injection	Holoxan	BX	MP		D
	Powder for I.V. injection 2 g	Injection	Holoxan	BX	MP		D
Inotuzumab ozogamicin	Powder for I.V. infusion 1 mg	Injection	Besponsa	PF	MP	C9470 C9601	D
Ipilimumab	Injection concentrate for I.V. infusion 50 mg in 10 mL	Injection	Yervoy	BQ	MP	C6562 C6585 C8555 C11391 C11478 C11930 C13841	D
	Injection concentrate for I.V. infusion 200 mg in 40 mL	Injection	Yervoy	BQ	MP	C6562 C6585 C13841	D
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL	Injection	MEDITAB IRINOTECAN	LR	MP		D
			Omegapharm Irinotecan	OE	MP		D

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Methotrexate	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Irinotecan Accord	OC	MP		D
			Irinotecan Alphapharm	AF	MP		D
			MEDITAB IRINOTECAN	LR	MP		D
			Omegapharm Irinotecan	OE	MP		D
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Injection	Irinotecan Accord	OC	MP		D
			Irinotecan Alphapharm	AF	MP		D
	Injection 5 mg in 2 mL vial	Injection	DBL Methotrexate	PF	MP		C
			DBL Methotrexate	PF	MP		C
	Injection 50 mg in 2 mL vial	Injection	Methotrexate Accord	OD	MP		C
			DBL Methotrexate	PF	MP		C
	Solution concentrate for I.V. infusion 500 mg in 20 mL vial	Injection	DBL Methotrexate	PF	MP		C
	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial	Injection	DBL Methotrexate	PF	MP		PB
Methotrexate Accord			OD	MP		PB	
Pfizer Australia Pty Ltd			PF	MP		PB	

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution concentrate for I.V. infusion 5000 mg in 50 mL vial	Injection	Methotrexate Ebewe	SZ	MP		PB
Mitozantrone	Injection 20 mg (as hydrochloride) in 10 mL	Injection	Mitozantrone Ebewe	SZ	MP		D
			Onkotrone	BX	MP		D
Nivolumab	Injection 25 mg (as hydrochloride) in 12.5 mL	Injection	Onkotrone	BX	MP		D
	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C9216 C9252 C9298 C9299 C9312 C9321 C10119 C10120 C10155 C11468 C11477 C11985 C13433 C13445 C13839 C13852 C13853 C13863 C13888 C13900 C14001	D
	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C9216 C9252 C9298 C9299 C9312 C9321 C10119 C10120 C10155 C11468 C11477 C11985 C13433 C13445 C13839 C13852 C13853 C13863 C13888 C13900 C14001	D
Obinutuzumab	Solution for I.V. infusion 1000 mg in 40 mL	Injection	Gazyva	RO	MP	C11015 C11052 C11755 C11785 C11787 C11815	D

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Oxaliplatin	Solution concentrate for I.V. infusion 100 mg in 20 mL	Injection	DBL Oxaliplatin Concentrate	PF	MP		D
			Oxaliplatin Accord	OC	MP		D
	Solution concentrate for I.V. infusion 200 mg in 40 mL	Injection	Oxaliplatin SUN	RA	MP		D
			Oxaliplatin SUN	RA	MP		D
Paclitaxel	Solution concentrate for I.V. infusion 300 mg in 50 mL	Injection	Paclitaxel Accord	OC	MP		D
			Paclitaxel Ebewe	SZ	MP		D
Paclitaxel, nanoparticle albumin-bound	Powder for I.V. injection containing 100 mg paclitaxel	Injection	Abraxane	TS	MP	C4657 C6106 C6119	D
Panitumumab	Solution concentrate for I.V. infusion 100 mg in 5 mL	Injection	Vectibix	AN	MP	C5452 C5526 C12035 C12066	D
	Solution concentrate for I.V. infusion 400 mg in 20 mL	Injection	Vectibix	AN	MP	C5452 C5526 C12035 C12066	D
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C10676 C10687 C10688 C10689 C10695 C10696 C10701 C10705 C13431 C13432 C13436 C13437 C13726 C13727 C13728 C13730 C13731 C13732 C13735 C13736 C13738 C13739 C13741 C13948 C13949 C13986 C14027 C14028	D

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only	
						C14044		
Pemetrexed	Powder for I.V. infusion 100 mg (as disodium)	Injection	Pemetrexed Accord	OD	MP		D	
			Pemetrexed-AFT	AE	MP		D	
			Pemetrexed SUN	RA	MP		D	
	Powder for I.V. infusion 500 mg (as disodium)	Injection	Pemetrexed Accord	OD	MP		D	
			Pemetrexed-AFT	AE	MP		D	
			Pemetrexed APOTEX	TX	MP		D	
			Pemetrexed SUN	RA	MP		D	
	Powder for I.V. infusion 1 g (as disodium)	Injection	Pemetrexed Accord	OD	MP		D	
			Pemetrexed SUN	RA	MP		D	
	Solution concentrate for I.V. infusion 100 mg (as disodium) in 4 mL	Injection	Pemetrexed Ever Pharma	IT	MP		D	
			Solution concentrate for I.V. infusion 500 mg (as disodium) in 20mL	Pemetrexed Ever Pharma	IT	MP		D
				Solution concentrate for I.V. infusion 1 g (as disodium) in 40 mL	Pemetrexed Ever Pharma	IT	MP	
Pertuzumab	Solution for I.V. infusion 420 mg in 14 mL	Injection	Perjeta	RO	MP	C10414 C13018	D	
Pralatrexate	Solution for I.V. infusion 20 mg in 1 mL	Injection	Folotyn	MF	MP	C7526 C7558	D	
Raltitrexed	Powder for I.V. infusion 2 mg in single use vial	Injection	Tomudex	PF	MP		D	
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Riximyo	SZ	MP		D	

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Ruxience	PF	MP		D
			Truxima	EW	MP		D
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Riximyo	SZ	MP		D
			Ruxience	PF	MP		D
			Truxima	EW	MP		D
Sacituzumab govitecan	Powder for injection 180 mg	Injection	Trodely	GI	MP	C12656 C12669	D
Topotecan	Powder for I.V. infusion 4 mg (as hydrochloride)	Injection	Hycamtin	SZ	MP		D
	Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride)	Injection	Topotecan Accord	OC	MP		D
Trabectedin	Powder for I.V. infusion 1 mg	Injection	Yondelis	ZL	MP	C14188 C14196 C14197	D
Trastuzumab	Powder for I.V. infusion 60 mg	Injection	Trazimera	PF	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
	Powder for I.V. infusion 150 mg	Injection	Herzuma	EW	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
			Kanjinti	JU	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
			Ogivri	AF	MP	C9349 C9353 C9571 C9573 C10213 C10293	PB

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy pharmaceutical benefits and related information **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
						C10294 C10296	
			Ontruzant	OQ	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
			Trazimera	PF	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
	Powder for I.V. infusion 420 mg	Injection	Kanjinti	JU	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
	Powder for I.V. infusion 440 mg with diluent	Injection	Herzuma	EW	MP	C9349 C9353 C9571 C9573 C10213 C10293 C10294 C10296	PB
Trastuzumab emtansine	Powder for I.V. infusion 100 mg	Injection	Kadcyla	RO	MP	C10295 C12989 C13004 C13017	D
	Powder for I.V. infusion 160 mg	Injection	Kadcyla	RO	MP	C10295 C12989 C13004 C13017	D
Vinblastine	Solution for I.V. injection containing vinblastine sulfate 10 mg in 10 mL	Injection	DBL Vinblastine	PF	MP		D
Vincristine	I.V. injection containing vincristine sulfate 1 mg in 1 mL	Injection	DBL Vincristine Sulfate	PF	MP		D
Vinorelbine	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	Injection	Navelbine	FB	MP		PB
			Vinorelbine Ebewe	SZ	MP		PB

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	Injection	Navelbine	FB	MP		PB
			Vinorelbine Ebewe	SZ	MP		PB

Part 2—Chemotherapy drugs and related information

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Arsenic	P4793 P5997	18	89
	P6018	18	140
Atezolizumab	P10206 P10939	1200	3
	P10521	1200	4
	P10125 P13443 P13448	1200	5
	P10216 P10297 P13442	1200	7
	P10917	1200	8
	P10509 P13446	1680	3
	P10215 P10257 P10972 P13451	1680	5
Avelumab	P13303 P13313	800	7
	P13290	800	11
	P8947	1200	8
	P10023	1200	11
Bendamustine		200	11
Bevacizumab		1800	7
Bleomycin		30000	11
Blinatumomab	P9911	651	0
	P9519	784	0
	P9936 P9937	784	1
	P9369	784	2
Bortezomib		3000	15
Brentuximab vedotin	P13179	180	3
	P13181	180	11
	P13212	200	1
	P13182 P13209 P13259	200	3
	P13134	200	5
	P13208 P13231 P13261	200	11
Cabazitaxel		55	5

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs
Part 2 Chemotherapy drugs and related information

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Carboplatin		900	5
Carfilzomib	P12930 P12934	120	17
	P12694 P12849	160	8
Cemiplimab	P13419	350	2
	P13373 P13766	350	6
	P13322 P13411	350	7
Cetuximab	P4788	550	5
	P12016 P12470	550	11
	P4912	550	18
	P4785 P4794 P4908 P12045 P12483	880	0
Cisplatin		220	14
Cladribine		17	6
Cyclophosphamide		2800	17
Cytarabine		7000	15
Daratumumab	P12845	1920	4
	P12691	1920	5
	P12844	1920	7
	P13752	1920	8
Docetaxel		250	5
Doxorubicin		135	11
Doxorubicin - pegylated liposomal		100	5
Durvalumab		1500	4
Elotuzumab	P12847	1200	5
	P12891	1200	9
Epirubicin		220	5
Eribulin	P7258 P7280	3	7
	P4649	3	13
Etoposide		440	14
Fludarabine		55	29
Fluorouracil	P6297	1000	23
	P6266	5500	11
Gemcitabine		3000	17

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy drugs and related information **Part 2**

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Gemtuzumab ozogamicin	P12566	5	1
	P12559	5	2
Idarubicin		30	5
Ifosfamide		4000	19
Inotuzumab ozogamicin	P9601	2820	4
	P9470	3384	2
Ipilimumab	P8555 P11930	120	3
	P11391 P11478	120	4
	P6562 P6585 P13841	360	3
Irinotecan		800	11
Methotrexate		250	5
	P6276	20000	0
Mitozantrone		30	5
Nivolumab	P13852 P13853	120	3
	P14001	360	3
	P11985	360	8
	P11468 P13433	360	13
	P10119 P10120 P13900	480	5
	P9216 P9312 P10155 P13445	480	8
	P9252 P9298 P9299 P9321 P11477 P13839 P13863	480	11
	P13888	480	13
Obinutuzumab	P11785 P11787	1000	5
	P11052 P11755	1000	7
	P11015	1000	8
	P11815	1000	9
Oxaliplatin		300	11
Paclitaxel		450	3
Paclitaxel, nanoparticle albumin-bound	P4657	275	11
	P6106 P6119	580	5
Panitumumab	P12035 P12066	720	5

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs
Part 2 Chemotherapy drugs and related information

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Pembrolizumab	P5452 P5526	720	9
	P10696	200	5
	P13431 P13432	200	6
	P10687 P10695 P10705	200	7
	P10689	400	2
	P10676 P10688 P10701 P13436 P13437	400	3
	P13726 P13727 P13728 P13730 P13731 P13732 P13735 P13736 P13738 P13739 P13741 P13948 P13949 P13986 P14027 P14028 P14044	400	6
Pemetrexed		1100	5
Pertuzumab	P10414	420	3
	P13018	840	0
Pralatrexate	P7558	80	5
	P7526	80	11
Raltitrexed		7	8
Rituximab		800	11
Sacituzumab govitecan	P12656	1200	7
	P12669	1200	13
Topotecan		3500	17
Trabectedin	P14196	3250	3
	P14188 P14197	3250	7
Trastuzumab	P10213	250	9
	P10296	500	0
	P9349 P9571 P10294	750	3
	P9353 P9573 P10293	1000	0
Trastuzumab emtansine	P10295 P13004	450	6
	P12989 P13017	450	8
Vinblastine		20	17

Chemotherapy pharmaceutical benefits and chemotherapy drugs **Schedule 1**
Chemotherapy drugs and related information **Part 2**

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Vincristine		2	7
Vinorelbine		70	7

Schedule 2—Related pharmaceutical benefits

(sections 3, 4, 6, 8, 10, 12, 13 and 22)

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Aprepitant	Capsule 165 mg	Oral	Aprepitant APOTEX	TX	MP	C4216 C4223 C6383 C6464		1	5	C
			APREPITANT SCP	XC	MP	C4216 C4223 C6383 C6464		1	5	C
Daratumumab	Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL	Injection	Darzalex SC	JC	MP	C12691 C12842 C12845 C13752 C13774 C13944 C14015	P12845	1	4	
					MP	C12691 C12842 C12845 C13752 C13774 C13944 C14015	P12691 P13774	1	5	
					MP	C12691 C12842 C12845 C13752 C13774 C13944 C14015	P12842	1	7	
					MP	C12691 C12842 C12845 C13752 C13774 C13944 C14015	P13752	1	8	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					MP	C12691 C12842 C12845 C13752 C13774 C13944 C14015	P13944 P14015	1	15	
Folinic acid	Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL		Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	MP			10	2	
	Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL	Injection	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	MP			10	1	
	Tablet containing calcium folinate equivalent to 15 mg folinic acid	Oral	Leucovorin Calcium (Hospira Pty Limited)	PF	MP	C5973		10	0	C
Fosaprepitant	Powder for I.V. infusion 150 mg	Injection	Emend IV	MK	MP	C6852 C6886 C6887 C6891		1	5	
			FOSAPREPITANT-A FT	AE	MP	C6852 C6886 C6887 C6891		1	5	
Granisetron	Concentrated injection 3 mg (as hydrochloride) in 3 mL	Injection	Granisetron Kabi	PK	MP	C4139		1	0	C
			Granisetron-AFT	AE	MP	C4139		1	0	C

Schedule 2 Related pharmaceutical benefits

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Kytril	IX	MP	C4139		1	0	C
	Tablet 2 mg (as hydrochloride)	Oral	Kytril	IX	MP	C4139		2	0	C
Mesna	Solution for I.V. injection 400 mg in 4 mL ampoule	Injection	Uromitexan	BX	MP	C5130		15	5	C
	Solution for I.V. injection 1 g in 10 mL ampoule	Injection	Uromitexan	BX	MP	C5130		15	5	C
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain	Single dose pack containing powder for irrigation 30 mg, 4 vials	Intravesical	VesiCulture	LM	MP	C5597		3	1	C
Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain	Vial containing powder for intravesical administration approximately 5 x 10 ⁸ CFU	Intravesical	OncoTICE	MK	MP	C5597		3	1	C
Netupitant with Palonosetron	Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)	Oral	Akynzeo	JZ	MP	C5991 C5994 C6879 C6937		1	5	
Ondansetron	Syrup 4 mg (as hydrochloride dihydrate) per	Oral	Zofran syrup 50 mL	AS	MP	C5778		1	0	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	5 mL, 50 mL									
	Tablet (orally disintegrating) 4 mg	Oral	APO-Ondansetron ODT	TX	MP	C5743		4	0	C
			APX-Ondansetron ODT	TY	MP	C5743		4	0	C
			Ondansetron AN ODT	EA	MP	C5743		4	0	C
			Ondansetron Mylan ODT	AF	MP	C5743		4	0	C
			Ondansetron ODT-DRLA	RZ	MP	C5743		4	0	C
			Ondansetron ODT Lupin	HQ	MP	C5743		4	0	C
			Ondansetron SZ ODT	HX	MP	C5743		4	0	C
			Zotren ODT	RF	MP	C5743		4	0	C
	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP	C5778		4	0	C
			APX-Ondansetron	TY	MP	C5778		4	0	C
			Ondansetron AN	EA	MP	C5778		4	0	C
			Ondansetron APOTEX	GX	MP	C5778		4	0	C
			Ondansetron Mylan Tablets	AF	MP	C5778		4	0	C

Schedule 2 Related pharmaceutical benefits

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Ondansetron SZ	HX	MP	C5778		4	0	C
			Ondansetron-DRLA	RZ	MP	C5778		4	0	C
			Zofran	AS	MP	C5778		4	0	C
			Zotren 4	RF	MP	C5778		4	0	C
	Tablet (orally disintegrating) 8 mg	Oral	APO-Ondansetron ODT	TX	MP	C5743		4	0	C
			APX-Ondansetron ODT	TY	MP	C5743		4	0	C
			Ondansetron AN ODT	EA	MP	C5743		4	0	C
			Ondansetron Mylan ODT	AF	MP	C5743		4	0	C
			Ondansetron ODT-DRLA	RZ	MP	C5743		4	0	C
			Ondansetron ODT Lupin	HQ	MP	C5743		4	0	C
			Ondansetron SZ ODT	HX	MP	C5743		4	0	C
			Zotren ODT	RF	MP	C5743		4	0	C
	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP	C5778		4	0	C
			APX-Ondansetron	TY	MP	C5778		4	0	C
			Ondansetron AN	EA	MP	C5778		4	0	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Ondansetron APOTEX	GX	MP	C5778		4	0	C
			Ondansetron Mylan Tablets	AF	MP	C5778		4	0	C
			Ondansetron SZ	HX	MP	C5778		4	0	C
			Ondansetron-DRLA	RZ	MP	C5778		4	0	C
			Zofran	AS	MP	C5778		4	0	C
			Zotren 8	RF	MP	C5778		4	0	C
	Wafer 4 mg	Oral	Zofran Zydys	AS	MP	C5743		4	0	C
	Wafer 8 mg	Oral	Zofran Zydys	AS	MP	C5743		4	0	C
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	Aloxi	MF	MP	C5805		1	0	C
			Palonosetron Dr.Reddy's	RZ	MP	C5805		1	0	C
Trastuzumab	Solution for subcutaneous injection containing trastuzumab 600 mg in 5 mL	Injection	Herceptin SC	RO	MP	C9353 C9462 C10212	P9353	1	0	
					MP	C9353 C9462 C10212	P9462 P10212	1	3	

Schedule 2 Related pharmaceutical benefits

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Tropisetron	I.V. injection 5 mg (as hydrochloride) in 5 mL	Injection	Tropisetron-AFT	AE	MP	C5749		1	0	C

Schedule 3—Responsible Person Codes

(section 6)

Code	Responsible Person	ABN
AE	AFT Pharmaceuticals (AU) Pty Ltd	29 105 636 413
AF	Alphapharm Pty Ltd	93 002 359 739
AN	Amgen Australia Pty Ltd	31 051 057 428
AP	AstraZeneca Pty Ltd	54 009 682 311
AS	Aspen Pharmacare Australia Pty Limited	51 096 236 985
BQ	Bristol-Myers Squibb Australia Pty Ltd	33 004 333 322
BX	Baxter Healthcare Pty Ltd	43 000 392 781
CR	Pharmacor Pty Limited	58 121 020 835
EA	Amneal Pharmaceuticals Pty Ltd	11 163 167 851
EI	Eisai Australia Pty Ltd	73 117 970 993
EW	Celltrion Healthcare Australia Pty Ltd	66 625 407 105
FB	Pierre Fabre Australia Pty Ltd	30 098 999 850
FF	Phebra Pty Ltd	99 059 357 890
GI	Gilead Sciences Pty Limited	71 072 611 708
GX	Apotex Pty Ltd	52 096 916 148
HQ	Generic Health Pty Ltd	93 110 617 859
HX	Sandoz Pty Ltd	60 075 449 553
IT	InterPharma Pty Ltd	19 99 877 899
IX	Clinect Pty Ltd	76 150 558 473
JC	Janssen-Cilag Pty Ltd	47 000 129 975
JO	Juno Pharmaceuticals Pty Ltd	55 156 303 650
JU	Juno Pharmaceuticals Pty Ltd	55 156 303 650
JZ	Juniper Biologics Pty Ltd	97 655 479 897
LM	Link Medical Products Pty Ltd	73 010 971 516
LR	Cipla Australia Pty Ltd	46 132 155 063
MF	Mundipharma Pty Limited	87 081 322 509
MK	Merck Sharp & Dohme (Australia) Pty Ltd	14 000 173 508
OC	Accord Healthcare Pty. Ltd.	49 110 502 513
OD	Accord Healthcare Pty. Ltd.	49 110 502 513
OE	Omegapharm Pty Ltd	86 128 078 151

Schedule 3 Responsible Person Codes

Code	Responsible Person	ABN
OQ	Organon Pharma Pty Ltd	54 637 107 512
PF	Pfizer Australia Pty Ltd	50 008 422 348
PK	Fresenius Kabi Australia Pty Limited	39 109 383 593
RA	Sun Pharma ANZ Pty Ltd	17 110 871 826
RF	Arrow Pharma Pty Ltd	35 605 909 920
RO	Roche Products Pty Ltd	70 000 132 865
RQ	Reach Pharmaceuticals Pty Ltd	25 623 897 183
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd	16 120 092 408
SG	Merck Serono Australia Pty Ltd	72 006 900 830
SW	sanofi-aventis Australia Pty Ltd	31 008 558 807
SZ	Sandoz Pty Ltd	60 075 449 553
TB	Teva Pharma Australia Pty Ltd	41 169 715 664
TK	Takeda Pharmaceuticals Australia Pty Ltd	71 095 610 870
TS	Specialised Therapeutics Australia Pty Ltd	73 124 031 241
TX	Apotex Pty Ltd	52 096 916 148
TY	Apotex Pty Ltd	52 096 916 148
XC	Southern Cross Pharma Pty Ltd	47 094 447 677
ZL	Specialised Therapeutics Pharma Pty Ltd	77 609 261 430

Schedule 4—Circumstances and Purposes Codes

(sections 8 to 12, 22 and 24)

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Aprepitant	C4216		<p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4216
	C4223		<p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>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.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4223
	C6383		<p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6383

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C6464		<p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> <p>Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.</p> <p>Nausea and vomiting</p> <p>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND</p> <p>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.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> <p>Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6464
Arsenic	C4793	P4793	<p>Acute promyelocytic leukaemia</p> <p>Induction and consolidation treatment</p> <p>The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript; AND</p> <p>The condition must be relapsed; AND</p> <p>Patient must be arsenic naive at induction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4793
	C5997	P5997	<p>Acute promyelocytic leukaemia</p> <p>The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 5997
	C6018	P6018	<p>Acute promyelocytic leukaemia</p>	Compliance with Authority Required procedures -

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Atezolizumab	C10125	P10125	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.	Streamlined Authority Code 6018
			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
			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
			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
			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	Compliance with Authority Required procedures - Streamlined Authority Code 10216

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			treatment; AND Patient must have stable or responding disease.	
	C10257	P10257	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
	C10297	P10297	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; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have stable or responding disease.	Compliance with Authority Required procedures - Streamlined Authority Code 10297
	C10509	P10509	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	Extensive-stage small cell lung cancer 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10521
	C10917	P10917	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma	Compliance with Authority Required procedures -

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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	Streamlined Authority Code 10917
	C10939	P10939	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. 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10939
	C10972	P10972	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
	C13442	P13442	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	Compliance with Authority Required procedures - Streamlined Authority Code 13442

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.</p> <p>Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug.</p> <p>The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND</p> <p>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</p> <p>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</p> <p>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.</p>	
	C13443	P13443	<p>Locally advanced or metastatic non-small cell lung cancer</p> <p>Initial treatment - 3 weekly treatment regimen</p> <p>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</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The condition must have progressed on or after prior platinum based chemotherapy; OR</p> <p>The condition must have progressed after treatment with tepotinib.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13443
	C13446	P13446	<p>Locally advanced or metastatic non-small cell lung cancer</p> <p>Initial treatment - 4 weekly treatment regimen</p> <p>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</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The condition must have progressed on or after prior platinum based chemotherapy; OR</p> <p>The condition must have progressed after treatment with tepotinib.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13446
	C13448	P13448	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p>	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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 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.	Required procedures - Streamlined Authority Code 13448
	C13451	P13451	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
Avelumab	C8947	P8947	Stage IV (metastatic) Merkel Cell Carcinoma	Compliance with Authority

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Required procedures - Streamlined Authority Code 8947
	C10023	P10023	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 The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 10023
	C13290	P13290	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
	C13303	P13303	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Grandfathering treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2022; AND Patient must have received first-line platinum-based chemotherapy prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease following first-line platinum-based chemotherapy; AND Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-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 13303

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	
	C13313	P13313	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.	Compliance with Authority Required procedures - Streamlined Authority Code 13313
Bendamustine	C7943		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		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. 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.	Compliance with Authority Required procedures - Streamlined Authority Code 7944
	C7972		Previously untreated stage III or IV mantle cell lymphoma Induction treatment The condition must be CD20 positive; AND	Compliance with Authority Required procedures - Streamlined Authority

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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.	Code 7972
Bleomycin	C6224		Lymphoma	
	C6275		Germ cell neoplasms	
Blinatumomab	C9369	P9369	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
	C9519	P9519	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.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C9911	P9911	<p>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>Acute lymphoblastic leukaemia Induction treatment</p> <p>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</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND</p> <p>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND</p> <p>Patient must not have received more than 1 line of salvage therapy; AND</p> <p>Patient must not have received blinatumomab previously for the treatment of minimal residual disease; OR</p> <p>Patient must have had a relapse-free period of at least six months following completion of treatment with blinatumomab for minimal residual disease; AND</p> <p>The condition must have more than 5% blasts in bone marrow; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>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.</p> <p>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.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include:</p> <ol style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed 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 minimal residual disease 	Compliance with Written Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C9936	P9936	<p>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.</p> <p>Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Continuing treatment of previously detectable minimal 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 Patient must be minimal residual disease negative, defined as either undetectable using the same method used to determine original eligibility or less than 10⁻⁴(0.01%) blasts based on measurement in bone marrow; AND Patient must not develop 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. 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 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.</p>	Compliance with Authority Required procedures
	C9937	P9937	<p>Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL) Initial treatment of minimal 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 minimal residual disease defined as at least 10⁻⁴(0.01%) blasts 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 or as subsequent salvage therapy, whichever was the later, and measured using</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>polymerase chain reaction or flow cytometry; 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. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Minimal 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.</p>	
Bortezomib	C11099		Multiple myeloma	
	C13745		<p>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.</p>	
Brentuximab vedotin	C13134	P13134	<p>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</p>	Compliance with Written Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13179	P13179	<p>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).</p> <p>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 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).</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13181	P13181	<p>CD30 positive cutaneous T-cell lymphoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved an objective response with this drug; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The treatment must not exceed 12 cycles under this restriction in a lifetime.</p> <p>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.</p>	Compliance with Authority Required procedures
	C13182	P13182	<p>CD30 positive systemic anaplastic large cell lymphoma</p> <p>Initial treatment</p> <p>The treatment must be for curative intent; AND</p> <p>Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND</p> <p>Patient must demonstrate relapsed or chemotherapy-refractory disease; AND</p> <p>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</p> <p>The treatment must not exceed 4 cycles under this restriction.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and</p> <p>(b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and</p> <p>(c) Dates of commencement and completion of front-line curative intent chemotherapy; and</p> <p>(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.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
	C13208	P13208	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Continuing treatment</p>	Compliance with Authority

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 12 cycles of treatment under this restriction.</p> <p>The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.</p>	Required procedures
	C13209	P13209	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Initial treatment</p> <p>Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND</p> <p>Patient must not be suitable for ASCT for this condition; OR</p> <p>Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND</p> <p>Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; OR</p> <p>Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; AND</p> <p>Patient must not receive more than 4 cycles of treatment under this restriction.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
	C13212	P13212	<p>CD30 positive peripheral T-cell lymphoma, non-cutaneous type</p> <p>Continuing treatment</p> <p>The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND</p> <p>Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication; AND</p> <p>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</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as:</p> <p>(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</p> <p>(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.</p>	
	C13231	P13231	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Continuing treatment</p> <p>Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND</p> <p>Patient must not be suitable for ASCT for this condition; OR</p> <p>Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 12 cycles of treatment under this restriction.</p> <p>The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.</p>	Compliance with Authority Required procedures
	C13259	P13259	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Initial treatment</p> <p>Patient must have undergone a primary autologous stem cell transplant (ASCT); AND</p> <p>Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; OR</p> <p>Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT; AND</p>	Compliance with Written Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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).</p>	
	C13261	P13261	<p>CD30 positive systemic anaplastic large cell lymphoma Continuing treatment Patient must not have developed disease progression while 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; AND The treatment must not exceed 12 cycles under this restriction in a lifetime.</p>	Compliance with Authority Required procedures
Cabazitaxel	C13207		<p>Castration resistant metastatic carcinoma of the prostate The treatment must be in combination with prednisone or prednisolone; AND 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13207
Carfilzomib	C12694	P12694	<p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12694

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
	C12849	P12849	<p>Multiple myeloma Continuing treatment - once 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 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).</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12849

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C12930	P12930	<p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12930
	C12934	P12934	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12934

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
Cemiplimab	C13322	P13322	<p>Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised therapy with this drug for this condition prior to 1 November 2022; AND</p> <p>The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy; AND</p> <p>Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>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.</p>	Compliance with Authority Required procedures
	C13373	P13373	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment - 3 weekly treatment regimen</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13373

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	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 a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.	
	C13411	P13411	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	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
	C13766	P13766	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 express programmed cell death ligand 1 (PD-L1) with a tumour proportion score (TPS) of at least 50% in the tumour sample. 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 be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed a total of 7 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 13766

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Cetuximab	C4785	P4785	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	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
	C4794	P4794	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	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
	C4912	P4912	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

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C12016	P12016	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
	C12045	P12045	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
	C12470	P12470	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	Metastatic colorectal cancer Initial treatment	Compliance with Authority Required procedures -

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			The treatment must be in combination with PBS-subsidised encorafenib for this condition.	Streamlined Authority Code 12483
Cladribine	C6265		Hairy cell leukaemia	Compliance with Authority Required procedures - Streamlined Authority Code 6265
Daratumumab	C12691	P12691	<p>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 (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
	C12842	P12842	<p>Relapsed and/or refractory multiple myeloma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021; AND Patient must have met all initial treatment PBS-eligibility criteria applying to a</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.</p> <p>Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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);</p>	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.</p> <p>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.</p> <p>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.</p>	
	C12844	P12844	<p>Relapsed and/or refractory multiple myeloma</p> <p>Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2021; AND</p> <p>Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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.	
	C12845	P12845	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 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
	C13752	P13752	Relapsed and/or refractory multiple myeloma 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	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.</p> <p>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.</p> <p>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.</p>	
	C13774	P13774	<p>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 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.</p>	Compliance with Authority Required procedures
	C13944	P13944	<p>Newly diagnosed systemic light chain amyloidosis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023; AND The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary</p>	Compliance with Written Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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; AND</p> <p>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.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:</p> <p>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</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Determine an appropriate number of repeat prescriptions for this authority application in line with either:</p> <p>(i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or</p> <p>(ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.</p>	
	C14015	P14015	<p>Newly diagnosed systemic light chain amyloidosis</p> <p>Initial treatment from week 0 to week 24</p> <p>The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND</p> <p>The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.</p> <p>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</p> <p>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.</p> <p>The authority application must be made via the Online PBS Authorities System (real time</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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).	
Durvalumab	C10126		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 Patient must not 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10126
	C12271		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
Elotuzumab	C12847	P12847	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:	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
	C12891	P12891	<p>Relapsed and/or refractory multiple myeloma Initial treatment</p> <p>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 have undergone or be ineligible for a stem cell transplant; AND Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	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.	
Eribulin	C4649	P4649	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
	C7258	P7258	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	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
Fluorouracil	C6266	P6266	Patients requiring administration of fluorouracil by intravenous infusion	
	C6297	P6297	Patients requiring administration of fluorouracil by intravenous injection	
Folinic acid	C5973		Megaloblastic anaemias The condition must be a result of folic acid deficiency from the use of folic acid antagonists.	
Fosaprepitant	C6852		Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy;	Compliance with Authority Required procedures -

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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.</p>	Streamlined Authority Code 6852
	C6886		<p>Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6886
	C6887		<p>Nausea and vomiting The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6887

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C6891		<p>Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.</p> <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6891
Gemtuzumab ozogamicin	C12559	P12559	<p>Acute Myeloid Leukaemia</p> <p>Induction treatment</p> <p>Patient must have confirmed CD33-positive AML prior to initiation of treatment; AND</p> <p>The condition must be de novo; AND</p> <p>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</p> <p>Patient must have confirmed intermediate/favourable cytogenetic risk; OR</p> <p>Patient must have unknown cytogenetic risk due to inconclusive test results; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND</p> <p>The condition must not be acute promyelocytic leukaemia; AND</p> <p>The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline; AND</p> <p>The treatment must not be used in combination with a tyrosine kinase inhibitor; AND</p> <p>The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive; AND</p> <p>Patient must not receive more than 1 induction cycle under this restriction in a lifetime.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures
	C12566	P12566	<p>Acute Myeloid Leukaemia</p> <p>Consolidation treatment</p> <p>Patient must have achieved a complete remission following induction treatment with this drug for this condition; AND</p> <p>The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline; AND</p> <p>Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime.</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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.</p> <p>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.</p> <p>Progressive disease is defined as the presence of any of the following:</p> <p>a) Leukaemic cells in the CSF;</p> <p>b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;</p> <p>c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;</p> <p>d) Extramedullary leukaemia.</p>	
Granisetron	C4139		<p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.</p> <p>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</p>	
Idarubicin	C6247		<p>Acute myelogenous leukaemia (AML)</p>	
Inotuzumab ozogamicin	C9470	P9470	<p>Acute lymphoblastic leukaemia</p> <p>Induction treatment</p> <p>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</p> <p>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND</p> <p>Patient must not have received more than 1 line of salvage therapy; AND</p> <p>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND</p> <p>The condition must be CD22-positive; AND</p> <p>The condition must have more than 5% blasts in bone marrow; AND</p> <p>The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p>	<p>Compliance with Written Authority Required procedures</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>The authority application must be made in writing and must include:</p> <p>(1) two completed authority prescription forms;</p> <p>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and</p> <p>(3) evidence that the condition is CD22-positive; and</p> <p>(4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and</p> <p>(5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.</p> <p>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.</p> <p>Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.</p>	
	C9601	P9601	<p>Acute lymphoblastic leukaemia</p> <p>Consolidation treatment</p> <p>Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND</p> <p>Patient must have achieved a complete remission; OR</p> <p>Patient must have achieved a complete remission with partial haematological recovery; AND</p> <p>The treatment must not be more than 5 treatment cycles under this restriction in a lifetime; AND</p> <p>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The treatment must not exceed 0.5mg per m²for all doses within a treatment cycle</p> <p>Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.</p>	Compliance with Authority Required procedures
Ipilimumab	C6562	P6562	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Induction treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have received prior treatment with ipilimumab; AND</p> <p>The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6562

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C6585	P6585	<p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Unresectable Stage III or Stage IV malignant melanoma Re-induction treatment</p> <p>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.</p> <p>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.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6585
	C8555	P8555	<p>Stage IV clear cell variant renal cell carcinoma (RCC) Induction treatment</p> <p>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.</p> <p>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 8555
	C11391	P11391	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing combination treatment (with nivolumab) of first-line drug therapy</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 11391

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			extend beyond disease progression, whichever comes first; AND The treatment must be in combination with nivolumab.	
	C11478	P11478	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 (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.	Compliance with Authority Required procedures - Streamlined Authority Code 11478
	C11930	P11930	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
	C13841	P13841	Unresectable Stage III or Stage IV malignant melanoma Induction 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 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.	Compliance with Authority Required procedures - Streamlined Authority Code 13841

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Mesna	C5130		The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Urothelial toxicity Prophylaxis or reduction of toxicity The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.	
Methotrexate		P6276	Patients receiving treatment with a high dose regimen	
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain	C5597		Primary and relapsing superficial urothelial carcinoma of the bladder	
Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain	C5597		Primary and relapsing superficial urothelial carcinoma of the bladder	
Netupitant with Palonosetron	C5991		Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with 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 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5991
	C5994		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 dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline. No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5994

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C6879		<p>Nausea and vomiting</p> <p>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.</p> <p>No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6879
	C6937		<p>Nausea and vomiting</p> <p>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND</p> <p>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.</p> <p>No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 6937
Nivolumab	C9216	P9216	<p>Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx</p> <p>Initial treatment</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy; AND</p> <p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9216

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C9252	P9252	<p>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.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9252</p>
	C9298	P9298	<p>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.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9298</p>
	C9299	P9299	<p>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.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9299</p>
	C9312	P9312	<p>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.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 9312</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> <p>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.</p>	
	C9321	P9321	<p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Maintenance treatment</p> <p>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</p> <p>The treatment must be as monotherapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p> <p>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.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9321
	C10119	P10119	<p>Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma</p> <p>Initial treatment</p> <p>The treatment must be adjuvant to complete surgical resection; AND</p> <p>Patient must have a WHO performance status of 1 or less; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have received prior PBS-subsidised treatment for this condition; AND</p> <p>The treatment must commence within 12 weeks of complete resection; AND</p> <p>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.</p> <p>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.</p>	Compliance with Authority Required procedures
	C10120	P10120	<p>Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma</p> <p>Continuing treatment</p> <p>Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND</p> <p>Patient must not have experienced disease recurrence; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.</p> <p>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			under a weight based or flat dosing regimen.	
	C10155	P10155	<p>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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10155
	C11468	P11468	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 11468
	C11477	P11477	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 11477
	C11985	P11985	<p>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</p>	Compliance with Authority Required procedures - Streamlined Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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.	Code 11985
	C13433	P13433	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 The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND The treatment must be in combination with ipilimumab.	Compliance with Authority Required procedures - Streamlined Authority Code 13433
	C13445	P13445	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 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.	Compliance with Authority Required procedures - Streamlined Authority Code 13445
	C13839	P13839	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	Compliance with Authority Required procedures - Streamlined Authority Code 13839

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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.</p>	
	C13852	P13852	<p>Unresectable Stage III or Stage IV malignant melanoma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for combination induction therapy Patient must have received non-PBS-subsidised treatment with nivolumab in combination with ipilimumab for this PBS indication prior to 1 March 2023; AND Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to commencing non-PBS-subsidised treatment; 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13852
	C13853	P13853	<p>Unresectable Stage III or Stage IV malignant melanoma Induction 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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13853
	C13863	P13863	<p>Unresectable Stage III or Stage IV malignant melanoma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for</p>	Compliance with Authority Required procedures -

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>maintenance treatment Patient must have previously received of up to maximum 4 doses of PBS-subsidised ipilimumab combined therapy with non-PBS-subsidised nivolumab as induction for this condition prior to 1 March 2023; AND The treatment must be as monotherapy for this condition; AND Patient must not have developed disease progression while receiving 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.</p>	Streamlined Authority Code 13863
	C13888	P13888	<p>Advanced or metastatic gastro-oesophageal cancers The condition must be a gastro-oesophageal cancer type as specified in the drug's 'Indications' section of the approved Australian Product Information; AND The treatment must be prescribed in accordance with the drug's 'Indications' section of the approved Australian Production Information with respect to each of: (i) concomitant drugs/therapies, (ii) line of therapy (i.e. prior treatments, if any); AND 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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13888
	C13900	P13900	<p>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</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C14001	P14001	<p>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. 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.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14001
Obinutuzumab	C11015	P11015	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 11015
	C11052	P11052	<p>Chronic lymphocytic leukaemia (CLL) Combination use with chlorambucil only The condition must be CD20 positive; AND The condition must be previously untreated; AND Patient must be inappropriate for fludarabine based chemo-immunotherapy; AND The treatment must be in combination with chlorambucil; AND Patient must have a creatinine clearance 30 mL/min or greater; AND Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); OR</p>	Compliance with Authority Required procedures - Streamlined Authority Code 11052

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			Patient must have a creatinine clearance less than 70 mL/min. Treatment must be discontinued in patients who experience disease progression whilst on this treatment.	
	C11755	P11755	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	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 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.	Compliance with Authority Required procedures
	C11787	P11787	Stage II bulky or Stage III/IV follicular lymphoma Maintenance therapy Patient must have previously received PBS-subsidised treatment with this drug under the	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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.</p>	
	C11815	P11815	<p>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.</p>	Compliance with Authority Required procedures
Ondansetron	C5743		<p>Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</p>	
	C5778		<p>Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</p>	
Paclitaxel, nanoparticle albumin-bound	C4657	P4657	<p>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</p>	Compliance with Authority Required procedures - Streamlined Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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.	Code 4657
	C6106	P6106	Metastatic breast cancer	Compliance with Authority Required procedures - Streamlined Authority Code 6106
	C6119	P6119	HER2 positive breast cancer	Compliance with Authority Required procedures - Streamlined Authority Code 6119
Palonosetron	C5805		Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.	
Panitumumab	C5452	P5452	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	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	Compliance with Authority Required procedures - Streamlined Authority Code 5526

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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.</p>	
	C12035	P12035	<p>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. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 12035</p>
	C12066	P12066	<p>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 panitumumab. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 12066</p>

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Pembrolizumab	C10676	P10676	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
	C10687	P10687	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 3 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
	C10688	P10688	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
	C10689	P10689	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 6 weekly treatment regimen 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 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 10689

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C10695	P10695	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 3 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
	C10696	P10696	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 3 weekly treatment regimen 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 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10696
	C10701	P10701	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	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
	C13431	P13431	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	Compliance with Authority Required procedures - Streamlined Authority Code 13431

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13432	P13432	<p>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.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13432
	C13436	P13436	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13436
	C13437	P13437	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13437
	C13726	P13726	<p>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 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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13726

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13727	P13727	<p>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.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13727
	C13728	P13728	<p>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 -</p>	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13730	P13730	<p>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.</p> <p>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.</p>	Compliance with Authority Required procedures
	C13731	P13731	<p>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 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13731
	C13732	P13732	<p>Relapsed or refractory primary mediastinal B-cell 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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13732

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13735	P13735	<p>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.</p> <p>Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx 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 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.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13735
	C13736	P13736	<p>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.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13736
	C13738	P13738	<p>Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p>	Compliance with Authority Required procedures -

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2022; AND</p> <p>Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if treated in the locally advanced setting prior to non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must have been initiated as non-PBS-subsidised therapy as either: (i) the sole therapy where the condition expressed 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; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition.</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>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.</p>	Streamlined Authority Code 13738
	C13739	P13739	<p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The condition must have progressed on or after prior platinum based chemotherapy; OR</p> <p>The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; OR</p> <p>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</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>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.</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks -</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13739

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13741	P13741	<p>prescribe up to 3 repeat prescriptions.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13741
	C13948	P13948	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13948
	C13949	P13949	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13949

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13986	P13986	<p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR</p> <p>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</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>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.</p> <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023; AND</p> <p>Patient must have had 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 if not already documented; AND</p> <p>The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment, (v) treatment is occurring with a dosing regimen specified in this drug's approved Australian Product Information, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose.</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13986
	C14027	P14027	<p>Advanced, metastatic or recurrent endometrial carcinoma</p> <p>Initial treatment</p> <p>Patient must have received prior treatment with platinum-based chemotherapy; AND</p> <p>The condition must be untreated with each of: (i) programmed cell death-1/ligand-1</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14027

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			(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 to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	
	C14028	P14028	Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (v) disease progression has not occurred whilst on treatment, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose. 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 14028
	C14044	P14044	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	Compliance with Authority Required procedures - Streamlined Authority Code 14044

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Pertuzumab	C10414	P10414	<p>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</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>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.</p> <p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously been issued with an authority prescription for this drug for this condition; AND</p> <p>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND</p> <p>The treatment must be in combination with trastuzumab; AND</p> <p>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.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> <p>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.</p> <p>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.</p>	Compliance with Authority Required procedures
	C13018	P13018	<p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Initial treatment</p> <p>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</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>Patient must not have received prior anti-HER2 therapy for this condition; AND</p> <p>Patient must not have received prior chemotherapy for this condition; AND</p> <p>The treatment must be in combination with trastuzumab and a taxane; AND</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Pralatrexate	C7526	P7526	<p>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 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.</p> <p>Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma Continuing treatment</p> <p>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.</p>	Compliance with Authority Required procedures
	C7558	P7558	<p>Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma Initial treatment</p> <p>The condition must be relapsed or chemotherapy refractory; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy.</p>	Compliance with Authority Required procedures
Sacituzumab govitecan	C12656	P12656	<p>Unresectable locally advanced or metastatic triple-negative breast cancer Initial treatment</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12656
	C12669	P12669	<p>Unresectable locally advanced or metastatic triple-negative breast cancer Continuing treatment</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 12669

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Trabectedin	C14188	P14188	<p>condition; AND The treatment must be the sole PBS-subsidised therapy for this PBS indication.</p> <p>Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have been receiving treatment with this drug for this condition prior to 1 August 2023; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated; AND Patient must have received chemotherapy treatment including an anthracycline, prior to initiating non-PBS-subsidised treatment; 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; 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14188
	C14196	P14196	<p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14196
	C14197	P14197	<p>Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma 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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14197

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Trastuzumab	C9349	P9349	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	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), prior to initiating treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9353
	C9462	P9462	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
	C9571	P9571	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	Compliance with Authority Required procedures - Streamlined Authority Code 9571

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C9573	P9573	<p>Patient must not have progressive disease; AND</p> <p>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.</p> <p>Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction</p> <p>Initial treatment</p> <p>Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity as demonstrated by immunohistochemistry 2+ or more in tumour material; AND</p> <p>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</p> <p>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</p> <p>Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; OR</p> <p>Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil; AND</p> <p>Patient must not have previously received this drug for this condition; AND</p> <p>Patient must not have received prior chemotherapy for this condition; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>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.</p> <p>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9573
	C10212	P10212	<p>Early HER2 positive breast cancer</p> <p>3 weekly treatment regimen</p> <p>Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND</p> <p>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</p> <p>Patient must not receive more than 52 weeks of combined PBS-subsidised and</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10212

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			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.	
	C10213	P10213	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
	C10293	P10293	Early HER2 positive breast cancer Initial treatment (3 weekly 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. 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10293
	C10294	P10294	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	Compliance with Authority Required procedures - Streamlined Authority Code 10294

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
Trastuzumab emtansine	C10296	P10296	<p>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.</p> <p>Early HER2 positive breast cancer Initial treatment (weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 10296
	C10295	P10295	<p>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</p> <p>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.</p>	Compliance with Authority Required procedures
	C12989	P12989	<p>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</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances and Purposes Codes

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
			<p>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.</p>	
	C13004	P13004	<p>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 The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.</p>	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements (part of Circumstances)
	C13017	P13017	<p>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:</p> <p>(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.</p> <p>The pathology report must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer; AND</p> <p>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>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.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> <p>The treatment must not exceed a lifetime total of one continuous course for this PBS indication.</p>	Compliance with Authority Required procedures
Tropisetron	C5749		<p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.</p> <p>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.</p>	

Schedule 5—Patient contributions

(sections 54 to 58)

Listed Drug	Form	Manner of Administration	Brand	Quantity or Number of Units	Approved Ex-manufacturer Price	Claimed Ex-manufacturer Price
Ondansetron	Wafer 4 mg	Oral	Zofran Zydis	4	\$3.41	\$5.69
Ondansetron	Wafer 8 mg	Oral	Zofran Zydis	4	\$5.35	\$7.63

Endnotes

Endnote 1—About the endnotes

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

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

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

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

Editorial changes

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

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

Misdescribed amendments

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

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

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 79 of 2011	29 Nov 2011 (F2011L02491)	1 Dec 2011	
PB 100 of 2011	20 Dec 2011 (F2011L02756)	1 Jan 2012	—
PB 4 of 2012	23 Feb 2012 (F2012L00379)	1 Mar 2012	—
PB 18 of 2012	29 Mar 2012 (F2012L00721)	1 Apr 2012	—
PB 32 of 2012	30 Apr 2012 (F2012L00951)	1 May 2012	—
PB 36 of 2012	30 May 2012 (F2012L01118)	1 June 2012	—
PB 40 of 2012	25 June 2012 (F2012L01332)	1 July 2012	—
PB 48 of 2012	27 July 2012 (F2012L01616)	1 Aug 2012	—
PB 65 of 2012	21 Aug 2012 (F2012L01730)	1 Sept 2012	—
PB 77 of 2012	28 Sept 2012 (F2012L01966)	1 Oct 2012	—
PB 97 of 2012	29 Nov 2012 (F2012L02290)	1 Dec 2012	—
PB 3 of 2013	14 Jan 2013 (F2013L00046)	1 Feb 2013	—
PB 11 of 2013	21 Feb 2013 (F2013L00254)	1 Mar 2013	—
PB 17 of 2013	27 Mar 2013 (F2013L00563)	1 Apr 2013	—
PB 25 of 2013	26 Apr 2013 (F2013L00691)	1 May 2013	—
PB 31 of 2013	24 May 2013 (F2013L00842)	1 June 2013	—
PB 36 of 2013	18 June 2013 (F2013L01039)	1 July 2013	—
PB 43 of 2013	29 July 2013 (F2013L01453)	1 Aug 2013	—
PB 57 of 2013	28 Aug 2013 (F2013L01631)	1 Sept 2013	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 64 of 2013	24 Sept 2013 (F2013L01735)	1 Oct 2013	—
PB 71 of 2013	18 Oct 2013 (F2013L01813)	1 Nov 2013	—
PB 79 of 2013	29 Nov 2013 (F2013L02023)	1 Dec 2013	—
PB 93 of 2013	24 Dec 2013 (F2013L02195)	1 Jan 2014	—
PB 5 of 2014	23 Jan 2014 (F2014L00079)	1 Feb 2014	—
PB 12 of 2014	26 Feb 2014 (F2014L00191)	1 Mar 2014	—
PB 21 of 2014	27 Mar 2014 (F2014L00360)	1 Apr 2014	—
PB 31 of 2014	28 Apr 2014 (F2014L00438)	1 May 2014	—
PB 41 of 2014	21 May 2014 (F2014L00578)	1 June 2014	—
PB 49 of 2014	1 July 2014 (F2014L00919)	1 July 2014	—
PB 56 of 2014	30 July 2014 (F2014L01053)	1 Aug 2014	—
PB 64 of 2014	25 Aug 2014 (F2014L01124)	1 Sept 2014	—
PB 78 of 2014	26 Sept 2014 (F2014L01291)	1 Oct 2014	—
PB 86 of 2014	29 Oct 2014 (F2014L01439)	1 Nov 2014 (s 2)	—
PB 94 of 2014	1 Dec 2014 (F2014L01615)	1 Dec 2014 (s 2)	—
PB 104 of 2014	24 Dec 2014 (F2014L01834)	1 Jan 2015 (s 2)	—
PB 4 of 2015	30 Jan 2015 (F2015L00083)	1 Feb 2015 (s 2)	—
PB 13 of 2015	27 Feb 2015 (F2015L00230)	1 Mar 2015 (s 2)	—
PB 31 of 2015	1 Apr 2015 (F2015L00434)	1 Apr 2015 (s 2)	—
PB 44 of 2015	29 Apr 2015 (F2015L00604)	1 May 2015 (s 2)	—
PB 51 of 2015	1 June 2015 (F2015L00769)	1 June 2015 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 59 of 2015	30 June 2015 (F2015L01060)	1 July 2015 (s 2)	—
PB 73 of 2015	31 July 2015 (F2015L01200)	1 Aug 2015 (s 2)	—
PB 84 of 2015	31 Aug 2015 (F2015L01361)	1 Sept 2015 (s 2)	—
PB 95 of 2015	1 Oct 2015 (F2015L01604)	1 Oct 2015 (s 2)	—
PB 105 of 2015	29 Oct 2015 (F2015L01715)	1 Nov 2015 (s 2)	—
PB 112 of 2015	1 Dec 2015 (F2015L01898)	1 Dec 2015 (s 2)	—
PB 122 of 2015	24 Dec 2015 (F2015L02132)	1 Jan 2016 (s 2)	—
PB 6 of 2016	1 Feb 2016 (F2016L00080)	1 Feb 2016 (s 2)	—
PB 14 of 2016	1 Mar 2016 (F2016L00213)	1 Mar 2016 (s 2)	—
PB 23 of 2016	1 Apr 2016 (F2016L00483)	1 Apr 2016 (s 2)	—
PB 34 of 2016	29 Apr 2016 (F2016L00605)	1 May 2016 (s 2)	—
PB 46 of 2016	31 May 2016 (F2016L00920)	1 June 2016 (s 2)	—
PB 56 of 2016	28 June 2016 (F2016L01092)	1 July 2016 (s 2)	—
PB 61 of 2016	1 July 2016 (F2016L01132)	1 July 2016 (s 2)	—
PB 68 of 2016	28 July 2016 (F2016L01241)	1 Aug 2016 (s 2)	—
PB 77 of 2016	31 Aug 2016 (F2016L01369)	1 Sept 2016 (s 2)	—
PB 85 of 2016	30 Sept 2016 (F2016L01567)	1 Oct 2016 (s 2)	—
PB 101 of 2016	30 Nov 2016 (F2016L01836)	1 Dec 2016 (s 2)	—
PB 114 of 2016	22 Dec 2016 (F2016L02032)	1 Jan 2017 (s 2)	—
PB 6 of 2017	27 Jan 2017 (F2017L00074)	1 Feb 2017 (s 2)	—
PB 13 of 2017	15 Mar 2017 (F2017L00226)	16 Mar 2017 (s 2)	—
PB 21 of 2017	31 Mar 2017 (F2017L00376)	1 Apr 2017 (s 2)	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 31 of 2017	28 Apr 2017 (F2017L00490)	Sch 1: 1 May 2017 (s 2(1) item 2) Sch 2: 1 Apr 2017 (s 2(1) item 3)	—
PB 40 of 2017	31 May 2017 (F2017L00624)	1 June 2017 (s 2)	—
PB 48 of 2017	30 June 2017 (F2017L00860)	1 July 2017 (s 2)	—
PB 58 of 2017	28 July 2017 (F2017L00963)	1 Aug 2017 (s 2)	—
PB 67 of 2017	31 Aug 2017 (F2017L01120)	1 Sept 2017 (s 2)	—
PB 76 of 2017	26 Sept 2017 (F2017L01261)	1 Oct 2017 (s 2)	—
PB 89 of 2017	30 Oct 2017 (F2017L01402)	1 Nov 2017 (s 2)	—
PB 96 of 2017	1 Dec 2017 (F2017L01557)	1 Dec 2017 (s 1)	—
PB 105 of 2017	18 Dec 2017 (F2017L01640)	1 Jan 2018 (s 2)	—
PB 7 of 2018	30 Jan 2018 (F2018L00066)	1 Feb 2018 (s 2)	—
PB 17 of 2018	28 Feb 2018 (F2018L00169)	1 Mar 2018 (s 2)	—
PB 23 of 2018	28 Mar 2018 (F2018L00424)	1 Apr 2018 (s 2)	—
PB 33 of 2018	30 Apr 2018 (F2018L00549)	1 May 2018 (s 2)	—
PB 41 of 2018	31 May 2018 (F2018L00682)	1 June 2018 (s 2)	—
PB 55 of 2018	29 June 2018 (F2018L00953)	1 July 2018 (s 2)	—
PB 68 of 2018	31 July 2018 (F2018L01067)	1 Aug 2018 (s 2)	—
PB 78 of 2018	30 Aug 2018 (F2018L01212)	1 Sept 2018 (s 2)	—
PB 86 of 2018	27 Sept 2018 (F2018L01362)	1 Oct 2018 (s 2)	—
PB 95 of 2018	29 Oct 2018 (F2018L01500)	1 Nov 2018 (s 2)	—
PB 103 of 2018	30 Nov 2018 (F2018L01638)	1 Dec 2018 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 112 of 2018	21 Dec 2018 (F2018L01818)	1 Jan 2019 (s 2)	—
PB 4 of 2019	31 Jan 2019 (F2019L00074)	1 Feb 2019 (s 2)	—
PB 14 of 2019	28 Feb 2019 (F2019L00218)	1 Mar 2019 (s 2)	—
PB 21 of 2019	29 Mar 2019 (F2019L00469)	1 Apr 2019 (s 2)	—
PB 32 of 2019	30 Apr 2019 (F2019L00664)	1 May 2019 (s 2)	—
PB 40 of 2019	30 May 2019 (F2019L00699)	1 June 2019 (s 2)	—
PB 49 of 2019	28 June 2019 (F2019L00924)	1 July 2019 (s 2)	—
PB 62 of 2019	31 July 2019 (F2019L01025)	1 Aug 2019 (s 2)	—
PB 71 of 2019	30 Aug 2019 (F2019L01125)	1 Sept 2019 (s 2)	—
PB 79 of 2019	30 Sept 2019 (F2019L01296)	1 Oct 2019 (s 2)	—
PB 88 of 2019	31 Oct 2019 (F2019L01390)	1 Nov 2019 (s 2)	—
PB 96 of 2019	29 Nov 2019 (F2019L01527)	1 Dec 2019 (s 2)	—
PB 107 of 2019	23 Dec 2019 (F2019L01702)	1 Jan 2020 (s 2)	—
PB 5 of 2020	31 Jan 2020 (F2020L00072)	1 Feb 2020 (s 2)	—
PB 18 of 2020	28 Feb 2020 (F2020L00187)	1 Mar 2020 (s 2)	—
PB 25 of 2020	31 Mar 2020 (F2020L00364)	1 Apr 2020 (s 2)	—
PB 38 of 2020	30 Apr 2020 (F2020L00525)	1 May 2020 (s 2)	—
PB 47 of 2020	29 May 2020 (F2020L00649)	1 June 2020 (s 2)	—
PB 60 of 2020	30 June 2020 (F2020L00852)	1 July 2020 (s 2)	—
PB 53 of 2020	20 Aug 2020 (F2020L01037)	21 Aug 2020 (s 2(1) item 1)	—
PB 83 of 2020	28 Aug 2020 (F2020L01091)	1 Sept 2020 (s 2)	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 94 of 2020	30 Sept 2020 (F2020L01262)	1 Oct 2020 (s 2)	—
PB 107 of 2020	30 Oct 2020 (F2020L01369)	1 Nov 2020 (s 2)	—
PB 116 of 2020	27 Nov 2020 (F2020L01501)	1 Dec 2020 (s 2)	—
PB 130 of 2020	22 Dec 2020 (F2020L01676)	1 Jan 2021 (s 2)	—
PB 5 of 2021	28 Jan 2021 (F2021L00081)	1 Feb 2021 (s 2)	—
PB 18 of 2021	28 Feb 2021 (F2021L00163)	1 Mar 2021 (s 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No.3) (PB 29 of 2021)	31 Mar 2021 (F2021L00402)	1 Apr 2021 (s 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No.4) (PB 43 of 2021)	30 Apr 2021 (F2021L00526)	1 May 2021 (s 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No.5) (PB 51 of 2021)	28 May 2021 (F2021L00665)	1 June 2021 (s 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No. 6) (PB 65 of 2021)	30 June 2021 (F2021L00907)	1 July 2021 (s 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No. 7) (PB 80 of 2021)	31 July 2021 (F2021L01056)	1 Aug 2021 (s 2)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No. 8) (PB 92 of 2021)	31 Aug 2021 (F2021L01215)	1 Sept 2021 (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 Instrument 2021 (No. 9) (PB 102 of 2021)	30 Sept 2021 (F2021L01372)	1 Oct 2021 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No. 10) (PB 114 of 2021)	31 Oct 2021 (F2021L01486)	1 Nov 2021 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No. 11) (PB 122 of 2021)	30 Nov 2021 (F2021L01648)	1 Dec 2021 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2021 (No. 12) (PB 132 of 2021)	24 Dec 2021 (F2021L01899)	1 Jan 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 1) (PB 6 of 2022)	31 Jan 2022 (F2022L00089)	1 Feb 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 2) (PB 15 of 2022)	28 Feb 2022 (F2022L00207)	1 Mar 2022 (s 2(1) item 1)	—
National Health Legislation Amendment (Authority Required Procedures for Prescriptions) Instrument 2022 (PB 21 of 2022)	28 Feb 2022 (F2022L00208)	Sch 1 (item 1): 1 Mar 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 3) (PB 28 of 2022)	31 Mar 2022 (F2022L00457)	1 Apr 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 4) (PB 38 of 2022)	29 Apr 2022 (F2022L00640)	1 May 2022 (s 2(1) item 1)	—

Endnotes

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 5) (PB 48 of 2022)	31 May 2022 (F2022L00731)	1 June 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 6) (PB 58 of 2022)	30 June 2022 (F2022L00898)	1 July 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 7) (PB 71 of 2022)	29 July 2022 (F2022L01016)	1 Aug 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 8) (PB 82 of 2022)	26 Aug 2022 (F2022L01111)	1 Sept 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 9) (PB 90 of 2022)	30 Sept 2022 (F2022L01294)	1 Oct 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 10) (PB 103 of 2022)	31 Oct 2022 (F2022L01409)	1 Nov 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 11) (PB 115 of 2022)	30 Nov 2022 (F2022L01544)	1 Dec 2022 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 12) (PB 124 of 2022)	23 Dec 2022 (F2022L01751)	1 Jan 2023 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 1) (PB 5 of 2023)	31 Jan 2023 (F2023L00064)	1 Feb 2023 (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 Instrument 2023 (No. 2) (PB 15 of 2023)	28 Feb 2023 (F2023L00174)	1 Mar 2023 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 3) (PB 25 of 2023)	31 Mar 2023 (F2023L00390)	1 Apr 2023 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 4) (PB 38 of 2023)	28 Apr 2023 (F2023L00494)	1 May 2023 (s 2(1) item 1)	—
National Health Legislation Amendment (Conditions of Approval for Approved Pharmacists) Instrument 2023 (PB 17 of 2023)	1 May 2023 (F2023L00511)	Sch 2 (items 2, 3): 1 June 2023 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 5) (PB 47 of 2023)	31 May 2023 (F2023L00650)	1 June 2023 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 6) (PB 59 of 2023)	30 June 2023 (F2023L00931)	1 July 2023 (s 2(1) item 1)	—
National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 7) (PB 72 of 2023)	31 July 2023 (F2023L01042)	1 Aug 2023 (s 2(1) item 1)	—

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
Division 1	
s 2.....	rep LA s 48D
s 3.....	am PB 18 of 2012; PB 40 of 2012; PB 48 of 2012; PB 36 of 2013; PB 49 of 2014; PB 31 of 2015; PB 59 of 2015; PB 56 of 2016; PB 61 of 2016; PB 77 of 2016; PB 48 of 2017; PB 96 of 2017; PB 55 of 2018; PB 103 of 2018; PB 49 of 2019; PB 60 of 2020; PB 53 of 2020; F2021L00665 ed C111 am F2021L00907; F2022L00898; F2023L00931
Division 2	
s 7.....	am PB 116 of 2020 ed C105
s 9.....	am PB 31 of 2015; PB 53 of 2020
s 10.....	am PB 31 of 2015
s 11.....	am PB 31 of 2015; PB 53 of 2020
s 12.....	am PB 31 of 2015
Part 2	
Division 1	
s 14.....	am PB 31 of 2015; PB 96 of 2017; PB 53 of 2020 ed C101
s 15.....	am PB 31 of 2015; PB 96 of 2017; PB 53 of 2020
s 16.....	rs PB 31 of 2015 am PB 96 of 2017; PB 53 of 2020
s 17.....	am PB 31 of 2015; PB 96 of 2017; PB 53 of 2020
s 18.....	am PB 31 of 2015; PB 53 of 2020
Division 2	
s 19.....	am PB 31 of 2015; PB 96 of 2017; PB 53 of 2020
s 20.....	rep PB 31 of 2015 ad PB 53 of 2020
s 21.....	rep PB 31 of 2015
Division 3	
s 22.....	am PB 31 of 2015; PB 34 of 2016; PB 53 of 2020; F2022L00208
s 23.....	rep PB 31 of 2015
s 24.....	rep PB 31 of 2015
s 25.....	rep PB 31 of 2015
s 26.....	rep PB 31 of 2015
s 27.....	rep PB 31 of 2015
s 28.....	rep PB 31 of 2015

Endnote 4—Amendment history

Provision affected	How affected
s 29.....	rep PB 31 of 2015
Part 3	
s 31.....	am PB 31 of 2015; PB 53 of 2020
s 33.....	am PB 31 of 2015; PB 53 of 2020
s 34.....	am PB 31 of 2015; PB 96 of 2017; PB 53 of 2020
s 35.....	am PB 31 of 2015
s 34A.....	ad PB 94, 2014 rs F2023L00511
s 35.....	rep PB 31 of 2015
Part 4	
Part 4 heading.....	rs PB 18 of 2012
Division 1	
Division 1 heading.....	rs PB 18 of 2012
s 36.....	am PB 31 of 2015
s 37.....	rs PB 18 of 2012 am PB 96 of 2017; PB 53 of 2020; F2021L00665 ed C111
s 38.....	rep PB 31 of 2015
s 39.....	rs PB 18 of 2012 am PB 31 of 2015; PB 96 of 2017
s 40.....	rep PB 31 of 2015
Division 2	
s 41A.....	ad F2023L00511
s 44.....	rep PB 31 of 2015
Division 2A	
Division 2A.....	ad PB 59 of 2015 rs PB 77 of 2016
s 46A.....	ad PB 59 of 2015 rs PB 77 of 2016 am PB 13 of 2017; PB 96 of 2017
s 46B.....	ad PB 59 of 2015 rs PB 77 of 2016 am PB 13 of 2017; PB 96 of 2017
s 46C.....	ad PB 59 of 2015 rep PB 77 of 2016
Division 3	
s 48.....	rs PB 59 of 2015 am PB 53 of 2020
Division 4	
s 52.....	am PB 31 of 2015

Endnotes

Endnote 4—Amendment history

Provision affected	How affected
Part 5	
s 56.....	rep PB 31 of 2015
s 57.....	am PB 31 of 2015
s 59.....	am PB 31 of 2015
Part 5A	
Part 5A.....	ad PB 53 of 2020
s 59A.....	ad PB 53 of 2020
Part 6	
s 60.....	rs PB 31 of 2015 am PB 21 of 2017; PB 96 of 2017; PB 53 of 2020
s 61.....	ad PB 59 of 2015 exp 1 Nov 2015 (s 61(3)) rep PB 77 of 2016
Schedule 1	
Schedule 1.....	am PB 100 of 2011; PB 4 of 2012; PB 18 of 2012; PB 32 of 2012; PB 36 of 2012; PB 40 of 2012; PB 48 of 2012; PB 65 of 2012; PB 77 of 2012; PB 97 of 2012; PB 3 of 2013; PB 11 of 2013; PB 17 of 2013; PB 25 of 2013; PB 31 of 2013; PB 36 of 2013; PB 43 of 2013; PB 57 of 2013; PB 64 of 2013; PB 71 of 2013; PB 79 of 2013; PB 5 of 2014; PB 12 of 2014; PB 21 of 2014; PB 31 of 2014; PB 41 of 2014; PB 49 of 2014; PB 56 of 2014; PB 64 of 2014; PB 78 of 2014; PB 86 of 2014; PB 94 of 2014; PB 104 of 2014 (Sch 1 item 1 md); PB 4 of 2015; PB 13 of 2015; PB 31 of 2015; PB 44 of 2015; PB 51 of 2015; PB 59 of 2015 (Sch 1 item 19 md); PB 73 of 2015; PB 84 of 2015 (Sch 1 item 1 md); PB 95 of 2015; PB 105 of 2015; PB 112 of 2015; PB 122 of 2015; PB 6 of 2016; PB 14 of 2016; PB 23 of 2016 (Sch 1 item 15 md); PB 34 of 2016; PB 46 of 2016; PB 56 of 2016; PB 68 of 2016; PB 77 of 2016; PB 85 of 2016; PB 101 of 2016; PB 114 of 2016; PB 6 of 2017; PB 21 of 2017; PB 31 of 2017; PB 40 of 2017; PB 48 of 2017; PB 58 of 2017; PB 67 of 2017; PB 76 of 2017; PB 89 of 2017; PB 96 of 2017; PB 105 of 2017; PB 7 of 2018; PB 17 of 2018; PB 23 of 2018; PB 33 of 2018; PB 55 of 2018; PB 68 of 2018; PB 78 of 2018; PB 86 of 2018; PB 95 of 2018; PB 103 of 2018; PB 112 of 2018 ed C82 am PB 4 of 2019; PB 14 of 2019; PB 21 of 2019; PB 32 of 2019; PB 40 of 2019; PB 49 of 2019; PB 62 of 2019; PB 71 of 2019; PB 79 of 2019; PB 88 of 2019; PB 96 of 2019; PB 107 of 2019; PB 5 of 2020; PB 18 of 2020; PB 25 of 2020; PB 38 of 2020; PB 47 of 2020; PB 60 of 2020; PB 83 of 2020; PB 94 of 2020; PB 107 of 2020; PB 116 of 2020, PB 130 of 2020; PB 5 of 2021; PB 18 of 2021; F2021L00402; F2021L00526; F2021L00665; F2021L00907; F2021L01056; F2021L01215; F2021L01372; F2021L01486; F2021L01648 ed C117 am F2021L01899; F2022L00089; F2022L00207; F2022L00457; F2022L00640; F2022L00731; F2022L00898; F2022L01016; F2022L01111; F2022L01294; F2022L01409; F2022L01544; F2022L01751; F2023L00174; F2023L00390; F2023L00494; F2023L00650; F2023L00931; F2023L01042
Schedule 2	
Schedule 2.....	am PB 40, 77 and 97 of 2012; PB 17, 25, 43, 57, 64 and 93 of 2013; PB 21 and 64 of 2014; PB 31, 51, 73, 95, 105 and 112 of 2015; PB 14, 23, 34, 46, 56, 68, 85 and 114 of

Endnote 4—Amendment history

Provision affected	How affected
	2016; PB 31 of 2017; PB 40 of 2017; PB 67 of 2017; PB 89 of 2017; PB 7 of 2018; PB 41 of 2018; PB 55 of 2018; PB 32 of 2019; PB 62 of 2019; PB 79 of 2019; PB 88 of 2019; PB 18 of 2020; PB 25 of 2020; PB 38 of 2020; PB 60 of 2020; PB 94 of 2020; PB 5 of 2021; F2021L01056; F2021L01215; F2021L01372; F2021L01486; F2021L01899; F2022L00089; F2022L00457; F2022L00640; F2022L00731 ed C123 am F2022L01751; F2023L00064; F2023L00494; F2023L00650
Schedule 3	
Schedule 3.....	am PB 32 and 40 of 2012; PB 3, 17 and 64 of 2013; PB 21, 31, 41, 49, 64, 78 and 94 of 2014; PB 59, 95 and 112 of 2015; PB 6, 14, 23, 34, 46, 68 and 114 of 2016; PB 6 of 2017; PB 40 of 2017; PB 58 of 2017; PB 89 of 2017; PB 33 of 2018; PB 78 of 2018; PB 86 of 2018; PB 103 of 2018; PB 112 of 2018; PB 4 of 2019; PB 32 of 2019; PB 40 of 2019; PB 71 of 2019; PB 79 of 2019; PB 88 of 2019; PB 107 of 2019; PB 18 of 2020; PB 94 of 2020; PB 116 of 2020, PB 130 of 2020; F2021L00907; F2021L01372; F2021L01486; F2021L01899; F2022L00089; F2022L00207; F2022L00640; F2022L01016; F2022L01294; F2022L01409; F2023L00650; F2023L01042
Schedule 4	
Schedule 4.....	am PB 100 of 2011; PB 4 of 2012; PB 48 of 2012; PB 77 of 2012; PB 97 of 2012; PB 25 of 2013; PB 43 of 2013; PB 79 of 2013; PB 93 of 2013; PB 21 of 2014; PB 56 of 2014; PB 78 of 2014; PB 86 of 2014; PB 94 of 2014; PB 104 of 2014; PB 4 of 2015; PB 13 of 2015; PB 31 of 2015; PB 51 of 2015; PB 59 of 2015; PB 73 of 2015; PB 84 of 2015; PB 95 of 2015; PB 105 of 2015; PB 112 of 2015; PB 122 of 2015; PB 14 of 2016; PB 23 of 2016 (Sch 1 item 15 md); PB 34 of 2016; PB 46 of 2016; PB 56 of 2016; PB 68 of 2016; PB 85 of 2016; PB 101 of 2016; PB 114 of 2016; PB 21 of 2017; PB 31 of 2017; PB 40 of 2017; PB 48 of 2017; PB 58 of 2017; PB 89 of 2017; PB 96 of 2017; PB 105 of 2017; PB 7 of 2018; PB 17 of 2018; PB 23 of 2018; PB 33 of 2018; PB 41 of 2018; PB 55 of 2018; PB 68 of 2018; PB 78 of 2018; PB 86 of 2018; PB 95 of 2018; PB 103 of 2018; PB 14 of 2019; PB 21 of 2019 ed C85 am PB 32 of 2019; PB 49 of 2019; PB 62 of 2019; PB 71 of 2019; PB 79 of 2019 ed C91 am PB 88 of 2019; PB 96 of 2019; PB 107 of 2019; PB 18 of 2020; PB 25 of 2020; PB 38 of 2020; PB 47 of 2020; PB 60 of 2020; PB 83 of 2020; PB 94 of 2020; PB 107 of 2020; PB 116 of 2020; PB 130 of 2020; PB 5 of 2021; F2021L00402 ed C109 am F2021L00526; F2021L00665; F2021L00907; F2021L01056; F2021L01215; F2021L01372; F2021L01486; F2021L01899; F2022L00207; F2022L00457; F2022L00640; F2022L00898; F2022L01016; F2022L01111; F2022L01294; F2022L01409; F2022L01544; F2022L01751; F2023L00174; F2023L00390; F2023L00494; F2023L00650; F2023L01042
Schedule 5	
Schedule 5.....	am PB 18 and 32 of 2012; PB 94 of 2014; PB 95 of 2015; PB 101 of 2016; PB 76 of 2017