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

made under subsection 100(1) of the

National Health Act 1953

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About this compilation

This compilation

This is a compilation of the *National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010)* that shows the text of the law as amended and in force on 1 July 2016 (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 Legislation 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 series page on the Legislation 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 series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Part 1—Preliminary

Division 1—General

1 Name of Special Arrangement

(1) This Special Arrangement is the *National Health (Highly specialised drugs program) Special Arrangement 2010*.

(2) This Special Arrangement may also be cited as PB 116 of 2010.

2 Commencement

This Special Arrangement commences on 1 December 2010.

3 Revocation

The following Instruments are revoked:

(a) the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010 (PB 63 of 2010)*; and

(b) the *National Health (Highly specialised drugs program for private hospitals) Special Arrangements Instrument 2010*.

Note: The Instrument mentioned in paragraph (b) is also known as PB 64 of 2010.

4 Definitions

In this Special Arrangement:

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

accredited prescriber of medication for the treatment of hepatitis B means a medical practitioner approved by a State or Territory to prescribe medication for the treatment of hepatitis B for this Special Arrangement.

accredited prescriber of medication for the treatment of Hepatitis C means a medical practitioner approved by a State or Territory to prescribe medication for the treatment of Hepatitis C for this Special Arrangement.

accredited prescriber of medication for the treatment of HIV or AIDS means a medical practitioner approved by a State or Territory to prescribe medication for the treatment of HIV or AIDS for this Special Arrangement.

accredited prescriber of medication for the treatment of schizophrenia means a medical practitioner approved by a State or Territory to prescribe medication for the treatment of schizophrenia for this Special Arrangement.

Act means the *National Health Act 1953*.

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affiliated specialist medical practitioner means a medical practitioner who:

(a) is affiliated with the hospital at or from which the patient is receiving treatment; and

(b) is either:

(i) a staff hospital specialist; or

(ii) a visiting or consulting specialist of the hospital.

approved hospital authority, for a hospital, means the hospital authority for the hospital that:

(a) is approved:

(i) by the Minister under section 94 of the Act; or

(ii) by the Chief Executive Medicare under section 52 of this Special Arrangement; or

(b) was approved under section 52 of the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010* and the approval:

(i) is not suspended; or

(ii) has not been revoked.

Note: The Instrument mentioned in paragraph (b) is also known as PB 63 of 2010.

approved private hospital means a private hospital that has an approved hospital authority.

approved public hospital means a public hospital that has an approved hospital authority.

authorised prescriber, for an HSD pharmaceutical benefit, means a person who is a kind of person identified by a prescriber code mentioned in the column in Schedule 1 headed 'Authorised Prescriber' for the benefit.

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 Palate Card;

(g) a DVA Gold Card;

(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.

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

a) abatacept
b) adalimumab
c) ambrisentan
d) azacitidine
e) bosentan
f) eculizumab
g) eltrombopag
h) epoprostenol
i) etanercept
j) iloprost
k) infliximab
l) ivacaftor
m) lenalidomide
n) macitentan
o) omalizumab
p) pomalidomide
q) rituximab
r) romiplostim
s) sildenafil
t) tadalafil
u) tocilizumab
v) vedolizumab

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

Department means the Department administered by the Minister who administers the *National Health Act 1953*.

dispensed price:

(a) for the supply of an HSD pharmaceutical benefit by a hospital authority for a public hospital—has the meaning given by section 37; and
(b) for the supply of an HSD pharmaceutical benefit by an approved hospital authority for a private hospital or by an approved pharmacist—has the meaning given by section 39.

eligible medical practitioner, for the prescription of an HSD pharmaceutical benefit under this Special Arrangement to an eligible patient, means a person:

(a) who is an affiliated specialist medical practitioner; or
(b) who is, for the prescription of medication for the treatment of HIV or AIDS—an accredited prescriber of medication for the treatment of HIV or AIDS; or
(ba) who is, for the prescription of medication for the treatment of hepatitis B—an accredited prescriber of medication for the treatment of hepatitis B; or

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(bb) who is, for the prescription of medication for the treatment of schizophrenia—an accredited prescriber of medication for the treatment of schizophrenia; or

(c) who is, for the prescription of medication for the treatment of hepatitis C:

(i) an accredited prescriber of medication for the treatment of hepatitis C; or

(ii) a medical practitioner for Daclatasvir, Ledipasvir with sofosbuvir, Ribavirin, and Sofosbuvir; or

(d) who is, for the prescription of medication for maintenance therapy if it is impractical to obtain a prescription from the treating affiliated specialist medical practitioner and the treating staff hospital specialist has agreed to the prescription—a medical practitioner; or

(e) who is, for the prescription of medication for maintenance therapy—a medical practitioner whom the Commonwealth and the State or Territory Government has agreed may give such a prescription.

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) if receiving treatment at or from a public hospital, is receiving medical treatment by a medical practitioner as:

(i) a non-admitted patient; or

(ii) a day admitted patient; or

(iii) a patient on discharge; or

(iv) an admitted patient who has been prescribed a HSD pharmaceutical benefit referred to in section 9A.

entitlement number, for a patient, means the number listed on the patient's benefit card.***General Statement for drugs for the treatment of hepatitis C*** means the statement set out in Schedule 3 Part 1.

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

Note: Special Arrangements under section 100 of the Act apply to pharmaceutical benefits with drugs that have been declared by the Minister under subsection 85(2) of the Act. The drugs in Schedule 1 have all been so declared.

hospital authority means:

(a) for a public hospital—the governing body of the hospital; or

(b) for a private hospital—the proprietor of the hospital.

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

item code, for a drug that has a particular form, manner of administration and brand, means the code for the form, manner of administration and brand for the drug set out in the Department's website.

Note: The website address is http://www.pbs.gov.au.

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medication chart prescription has the meaning given in the Regulations, but does not include a medication chart prescription for a person receiving treatment in a residential care service.

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

(a) adefovir dipivoxil
(b) entecavir monohydrate
(c) interferon alfa-2a
(d) interferon alfa-2b
(e) lamivudine
(f) peginterferon alfa-2a
(g) telbivudine
(h) tenofovir

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

(a) abacavir
(b) abacavir with lamivudine
(c) abacavir with lamivudine and zidovudine
(d) atazanavir
(e) azithromycin
(f) darunavir
(g) didanosine
(h) dolutegravir
(i) dolutegravir with abacavir and lamivudine
(j) doxorubicin, pegylated liposomal
(k) efavirenz
(l) emtricitabine
(m) enfuvirtide
(n) etravirine
(o) fosamprenavir
(p) foscarnet
(q) ganciclovir
(r) indinavir
(s) lamivudine
(t) lamivudine with zidovudine
(u) lopinavir with ritonavir
(v) maraviroc
(w) nevirapine
(x) raltegravir
(y) rifabutin
(z) rilpivirine
(za) ritonavir
(zb) saquinavir

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(zc) stavudine
(zd) tenofovir
(ze) tenofovir with emtricitabine
(zf) tenofovir with emtricitabine and efavirenz
(zg) tenofovir with emtricitabine, elvitegravir and cobicistat
(zh) tenofovir with emtricitabine and rilpivirine
(zi) valganciclovir
(zj) tipranavir
(zk) zidovudine

medication for the treatment of schizophrenia means clozapine.

non-CAR drug means a highly specialised drug that is not a complex authority required (CAR) drug.

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

prescriber code has the meaning given by paragraph 8(2)(b).

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

residential care service has the meaning given by the Regulations.

Regulations means the *National Health (Pharmaceutical Benefits) Regulations 1960*.

streamlined authority code means the number mentioned in subsection 13(1).

under co-payment data means information relating to a supply of a HSD pharmaceutical benefit by an approved pharmacist, approved medical practitioner or approved hospital authority for a hospital where a claim is not payable as the dispensed price for the supply of the HSD pharmaceutical benefit does not exceed the amount that the supplier was entitled to charge under subsection 46(2) or subsection 47(2) of this Special Arrangement.

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 ex-manufacturer price
- approved medical practitioner
- approved pharmacist
- claimed price
- hospital
- medical practitioner
- Chief Executive Medicare
- pack quantity
- pharmaceutical benefit
- pharmaceutical item
- private hospital
- proportional ex-manufacturer price
- public hospital.

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Division 2—HSD pharmaceutical benefits

5 Pharmaceutical benefits covered by this Special Arrangement

(1) This Special Arrangement applies to each HSD pharmaceutical benefit mentioned in Schedule 1.

(2) Each HSD pharmaceutical benefit to which this Special Arrangement applies is a brand of a listed drug mentioned in Schedule 1:

(a) in the form mentioned in Schedule 1 for the listed drug; and

(b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Note: Each listed drug mentioned in Schedule 1 is a highly specialised drug—see definition of ***highly specialised drug*** in section 4. Each listed drug has been declared by the Minister under subsection 85(2) of the Act. The form, manner of administration and brand mentioned in Schedule 1 have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

6 Application of Part VII of the Act

(1) Each HSD 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: See subsection 100(3) of the Act.

7 Responsible person

(1) If a code is mentioned in the column in Schedule 1 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 2 for the code, with the ABN, if any, mentioned in Schedule 2 for the person; and

(b) the pharmaceutical item is the listed drug mentioned in Schedule 1:

(i) in the form mentioned in Schedule 1 for the listed drug; and

(ii) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Note 1: An HSD pharmaceutical benefit mentioned in Schedule 1 is a brand of a pharmaceutical item.

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

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8 Authorised Prescriber

(1) Only an authorised prescriber may write a prescription for the supply of an HSD pharmaceutical benefit to an eligible patient.

(2) For this Special Arrangement:
  (a) only an eligible medical practitioner is an authorised prescriber; and
  (b) the ***prescriber code*** for the authorised prescriber is the letters 'EMP'.

(3) A reference in this Special Arrangement to an eligible medical practitioner is a reference to an authorised prescriber.

(4) For subsection (1), the HSD pharmaceutical benefit is the brand of the listed drug mentioned in Schedule 1:
  (a) in the form mentioned in Schedule 1 for the listed drug; and
  (b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

(5) Subsection 88(1) of the Act does not apply to the supply of an HSD pharmaceutical benefit under this Special Arrangement.

9 Prescription circumstances

(1) If at least 1 circumstances code is mentioned in the column in Schedule 1 headed 'Circumstances' for an HSD pharmaceutical benefit, the circumstances mentioned in Schedule 3 for the code are the circumstances in which a prescription for the supply of the HSD pharmaceutical benefit may be written.

(2) For subsection (1), the HSD pharmaceutical benefit is the brand of the listed drug mentioned in Schedule 1:
  (a) in the form mentioned in Schedule 1 for the listed drug; and
  (b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

9A HSD pharmaceutical benefits which may be supplied to public hospital admitted patients

The HSD pharmaceutical benefits which may be supplied to public hospital admitted patients under this Special Arrangement are referred to in the table below:
  (a) if a drug is referred to in the table below and paragraphs (b), (c) and (d) do not apply – all HSD pharmaceutical benefits containing that drug;
  (b) if a form of the drug is referred to in the table below and paragraphs (c) and (d) do not apply – all HSD pharmaceutical benefits containing that drug in that form;
  (c) if a manner of administration of that form of the drug is referred to in the table below and paragraph (d) does not apply – all HSD pharmaceutical benefits containing that drug in that form with that manner of administration;

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(d) if a brand of a drug in that form with that manner of administration is referred to in the table below – that brand of HSD pharmaceutical benefit containing that drug in that form with that manner of administration;

(e) if one or more circumstances and/or purposes code is identified in the table below – the HSD pharmaceutical benefit must be prescribed for one of those circumstances and/or purposes.

Drug	**Form**	**Manner of Administration**	**Brand**	**Circumstances Code**	**Purposes Code**
eculizumab					

Note: A circumstances and/or purposes code mentioned in the above table is the same circumstances and/or purposes code referred to in section 9 (circumstances code) or section 14 or section 15 (purposes code).

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Division 3—HSD Authority Required procedures

10 HSD Authority Required procedures

(1) This section applies to an HSD pharmaceutical benefit if the circumstances mentioned in Schedule 3 for a circumstances code mentioned in Schedule 1 for the HSD pharmaceutical benefit includes:
  (a) Compliance with Authority Required procedures;
  (b) Compliance with Written Authority Required procedures;
  (c) Compliance with Written or Telephone Authority Required procedures;
  (d) Compliance with modified Authority Required procedures.

(1A) If the circumstances mentioned in Schedule 3 for a circumstances code mentioned in Schedule 1 for a HSD pharmaceutical benefit include 'Compliance with Written or Telephone Authority Required procedures' then treat as if the words used are 'Compliance with Authority Required procedures'.

(2) The Authority Required procedures as provided for in sections 11 to 14 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* are to be followed.

(3) In addition to the requirements of subsection (2), where 'Compliance with modified Authority Required procedures' appears in the circumstances mentioned in Schedule 3 for the code, in addition to 'Compliance with Written or Telephone Authority Required procedures', any other requirement included in the circumstances is to be followed as part of the Authority Required procedures.

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Division 4—Maximum quantity and maximum number of repeats

14 Maximum quantity

(1) The maximum quantity or number of units of the pharmaceutical item in an HSD pharmaceutical benefit that may, in 1 prescription for the supply of the HSD pharmaceutical benefit, be directed to be supplied by an eligible medical practitioner is the quantity or number of units mentioned in the column in Schedule 1 headed 'Maximum Quantity' for the HSD pharmaceutical benefit.

(2) If at least 1 purposes code is mentioned in the column in Schedule 1 headed 'Purposes' for an HSD 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 3 for each code.

(3) If no purposes code is mentioned in the column in Schedule 1 headed 'Purposes', the quantity or number of units mentioned in the column in Schedule 1 headed 'Maximum Quantity' is the maximum for all purposes, other than a purpose for which a different maximum is mentioned for the same HSD pharmaceutical benefit.

(4) For subsection (1), the pharmaceutical item is the listed drug mentioned in Schedule 1:

(a) in the form mentioned in Schedule 1 for the listed drug; and

(b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

(5) For this section, the HSD pharmaceutical benefit is the brand of the listed drug mentioned in Schedule 1:

(a) in the form mentioned in Schedule 1 for the listed drug; and

(b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

(6) Subsection (1) applies, in relation to an HSD pharmaceutical benefit that has a CAR drug, subject to section 24.

Note 1: The maximum quantities and numbers of units mentioned in the column headed 'Maximum quantity' in Schedule 1 have been determined by the Minister under paragraph 85A(2)(a) of the Act.

Note 2: See also section 26.

(7) A determination made under paragraph 85A(2)(a) of the Act does not apply to an HSD pharmaceutical benefit supplied in accordance with this Special Arrangement in relation to the maximum quantity of the HSD pharmaceutical benefit that can be supplied under this Special Arrangement if the maximum quantity mentioned in the determination differs from the maximum quantity mentioned in this section.

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Section 15

15 Maximum number of repeats

(1) The maximum number of occasions an eligible medical practitioner may, in 1 prescription, direct that the supply of the pharmaceutical benefit be repeated is the number in the column in Schedule 1 headed 'Number of Repeats' for the pharmaceutical benefit.

(2) If at least 1 purposes code is mentioned in the column in Schedule 1 headed 'Purposes' for the pharmaceutical benefit, the number of repeats mentioned in the column in Schedule 1 headed 'Number of Repeats' is the maximum number for the particular purposes mentioned in Schedule 3 for each code.

(3) If no purposes code is mentioned in the column 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 pharmaceutical benefit.

(4) For this section, the pharmaceutical benefit is the brand of the listed drug mentioned in Schedule 1:
  (a) in the form mentioned in Schedule 1 for the listed drug; and
  (b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

(5) Subsection (1) applies, in relation to an HSD pharmaceutical benefit that has a CAR drug, subject to section 25.

Note: See also section 26.

(6) A determination made under paragraph 85A(2)(b) of the Act does not apply to an HSD pharmaceutical benefit supplied in accordance with this Special Arrangement in relation to the maximum number of occasions an eligible medical practitioner may, in 1 prescription, direct, under this Special Arrangement, that the supply of the HSD pharmaceutical benefit be repeated if the maximum number mentioned in the determination differs from the maximum number mentioned in this section.

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Division 5—Section 100 only

16 Section 100 only supply

(1) If the letter ‘D’ is mentioned in the column in Schedule 1 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) An HSD 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 Schedule 1 headed ‘Section 100 only’ for an HSD pharmaceutical benefit, the HSD pharmaceutical benefit may be supplied only in accordance with this Special Arrangement and any other Special Arrangement relating to the pharmaceutical benefit.

(4) An HSD 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 HSD pharmaceutical benefit can only be supplied under a section 100 Special Arrangement.

(5) If the letter ‘C’ is mentioned in the column in Schedule 1 headed ‘Section 100 only’ for an HSD pharmaceutical benefit, the HSD pharmaceutical benefit may be supplied in the circumstances mentioned in Schedule 3 for the circumstances code in the column headed ‘Circumstances’ only in accordance with this Special Arrangement and any other Special Arrangement relating to the HSD pharmaceutical benefit.

(6) An HSD 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 1 or more of the circumstances in which a prescription for the supply of the HSD pharmaceutical benefit may be written are circumstances in which the benefit can only be supplied under a section 100 Special Arrangement.

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Part 2—Supply of HSD pharmaceutical benefits

Division 1—General requirements for supply

17 Entitlement to HSD pharmaceutical benefits

Subject to this Special Arrangement, an eligible patient is entitled to be supplied an HSD pharmaceutical benefit under this Special Arrangement without payment or other consideration, other than a charge made in accordance with Part 6.

17A Modified application of paragraph 92A(1)(f) conditions of approval

(1) Section 8 of the conditions of approval for approved pharmacists under paragraph 92A(1)(f) of the Act does not apply to the supply of a HSD pharmaceutical benefit, once prepared as a final product ready for infusion to a person, when the HSD pharmaceutical benefit has a physical, chemical or biological stability restricting its clinically effective shelf life to 8 hours or less.

(2) For the purposes of this section, shelf life means the period of time that a medicine can be stored and still be considered safe and effective for use.

18 Supply of HSD pharmaceutical benefits under this Special Arrangement

(1) Subject to subsection (2), this Special Arrangement only applies to the supply of an HSD pharmaceutical benefit:
  (a) by an approved hospital authority for a public hospital to an eligible patient receiving treatment at or from an approved public hospital; or
  (b) by an approved hospital authority for a private hospital to an eligible patient receiving treatment at or from an approved private hospital; or
  (c) by an approved pharmacist to an eligible patient receiving treatment at or from a private hospital; or
  (d) if the HSD pharmaceutical benefit has a CAR drug—by an approved pharmacist to an eligible patient receiving treatment at or from an approved public hospital or an approved private hospital.

(2) Where an eligible patient receives treatment in or at or outside of an approved public hospital or an approved private hospital, then a supplier listed in paragraph (a) may supply, to the eligible patient, HSD pharmaceutical benefits that are referred to in paragraph (b):
  (a) The suppliers are:
    i. an approved pharmacist; or
    ii. an approved medical practitioner; or
    iii. an approved hospital authority;
  (b) The HSD pharmaceutical benefits are:
    i. medication for the treatment of hepatitis B;

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ii. medication for the treatment of HIV or AIDS, other than the pharmaceutical benefits containing the drugs azithromycin, doxorubicin - pegylated liposomal and rifabutin; and

iii. medication for the treatment of schizophrenia when used in continuing therapy.

(3) This section does not require an approved hospital authority or an approved pharmacist to supply the HSD pharmaceutical benefit directly to a patient.

(4) The HSD pharmaceutical benefit may be supplied by the approved hospital authority or approved pharmacist through an agent.

(5) Section 94 of the Act applies in a modified manner to pharmaceutical benefits supplied by an approved hospital authority under this Special Arrangement.

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Division 2—Repeat prescriptions

19 Application of regulation 25

Regulation 25 of the Regulations does not apply to the supply of HSD pharmaceutical benefits.

20 No repeats for visitors

An eligible medical practitioner must not write a repeat prescription for an HSD pharmaceutical benefit for a person who is a visitor to Australia even if the person is, in accordance with section 7 of the *Health Insurance Act 1973*, to be treated as an eligible person within the meaning of that Act.

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Division 3—Prescribing HSD pharmaceutical benefits that have non-CAR drugs

21 Methods of prescribing HSD pharmaceutical benefits that have non-CAR drugs

An eligible medical practitioner may prescribe an HSD pharmaceutical benefit that has a non-CAR drug under this Special Arrangement by:

(a) writing a prescription for the HSD pharmaceutical benefit in accordance with regulation 19 of the Regulations; or

(b) preparing a medication chart prescription for the HSD pharmaceutical benefit in accordance with regulation 19AA of the Regulations.

Note: An eligible medical practitioner may only prescribe more than the maximum quantity or more than the maximum number of repeats of an HSD pharmaceutical benefit that has a non-CAR drug in accordance with Regulation 13.

22A Information to be kept for prescription of HSD pharmaceutical benefits referred to in section 9A that have non-CAR drugs

(1) If an eligible medical practitioner prescribes a HSD pharmaceutical benefit referred to in section 9A for supply under Part VII of the Act, and that HSD pharmaceutical benefit has a non-CAR drug, then either the:

(a) eligible medical practitioner; or

(b) approved hospital authority treating the eligible patient;

must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes.

(2) These records must be kept for 2 years after the date the prescription to which the records relate is written.

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Division 4—Prescribing HSD pharmaceutical benefits that have CAR drugs

23 Prescriptions for HSD pharmaceutical benefits that have CAR drugs

An eligible medical practitioner may prescribe an HSD pharmaceutical benefit that has a CAR drug by writing a prescription for the HSD pharmaceutical benefit in accordance with regulation 19 of the Regulations.

23A Information to be kept for prescription of HSD pharmaceutical benefits referred to in section 9A that have CAR drugs

(1) If an eligible medical practitioner prescribes a HSD pharmaceutical benefit referred to in section 9A for supply under Part VII of the Act, and that HSD pharmaceutical benefit has a CAR drug, then either the:

(a) eligible medical practitioner; or

(b) approved hospital authority treating the eligible patient;

must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes.

(2) These records must be kept for 2 years after the date the prescription to which the records relate is written.

24 HSD pharmaceutical benefits that have CAR drugs—quantity exceptions

(1) An eligible medical practitioner may write a prescription for an HSD pharmaceutical benefit that has a CAR drug mentioned in subsection (2) to be supplied to an eligible patient on any 1 occasion only in accordance with the limitation mentioned in subsection (2) for each HSD pharmaceutical benefit mentioned in subsection (2).

(2) The drugs and limitations are as follows:

(a) for HSD pharmaceutical benefits that have the drug ambrisentan, bosentan, epoprostenol, etanercept, iloprost, sildenafil or tadalafil—a quantity of units sufficient for up to 1 month of treatment with the drug;

(b) for HSD pharmaceutical benefits that have the drug infliximab, for the treatment of an adult with severe active rheumatoid arthritis—a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 3 milligrams per kilogram;

(c) for HSD pharmaceutical benefits that have the drug infliximab, for the treatment of an adult with active ankylosing spondylitis, severe active psoriatic arthritis or severe chronic plaque psoriasis—a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 5 milligrams per kilogram;

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(d) for HSD pharmaceutical benefits that have the drug infliximab, for the treatment of a patient with refractory Crohn disease or fistulating Crohn disease—a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 5 milligrams per kilogram;

(e) for HSD pharmaceutical benefits that have the drug rituximab—a quantity of units sufficient to provide for a single dose;

(f) for HSD pharmaceutical benefits that have the drug abatacept—a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose;

(g) for HSD pharmaceutical benefits that have the drug tocilizumab, for the treatment of adult patients with severe active rheumatoid arthritis—a quantity of units that are sufficient, based on the weight of the patient and taking into account whether any other strength injections will contribute part of the dose, to provide for the whole or part of a single dose of 8 mg per kg;

(h) for HSD pharmaceutical benefits that have the drug adalimumab—a quantity of units that are sufficient, based on the weight of the patient, to provide for 2 doses;

(i) for HSD pharmaceutical benefits that have the drug lenalidomide, for the treatment of a patient with multiple myeloma:

(i) with the form Capsule 5 mg—up to 84 tablets;

(ii) with the form Capsule 10 mg—up to 42 tablets;

(iii) with the form Capsule 15 mg—up to 21 tablets;

(iv) with the form Capsule 25 mg—up to 21 tablets;

(j) for HSD pharmaceutical benefits that have the drug lenalidomide, for the treatment of a patient with myelodysplastic syndrome:

(i) with the form Capsule 5 mg—up to 21 tablets;

(ii) with the form Capsule 10 mg—up to 21 tablets;

(k) for HSD pharmaceutical benefits that have the drug azacitidine with the form Powder for injection 100mg—up to 14 units.

(l) for HSD pharmaceutical benefits that have the drug romiplostim, for initial treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP):

(i) at the time of the initial written authority application—a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 1 microgram per kilogram;

(ii) during the initial period of dose titration—a quantity of units sufficient to provide for a single dose;

(iii) for a patient whose dose has been stable for a period of 4 weeks—a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks.

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(m) for HSD pharmaceutical benefits that have the drug romiplostim, for initial PBS-subsidised treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with Romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment in the circumstances can be demonstrated to have been met at the time his or her treatment with Romiplostim was commenced:

(i) at the time of the initial written authority application—a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 1 microgram per kilogram;

(ii) during the initial period of dose titration—a quantity of units sufficient to provide for a single dose;

(iii) for a patient in the titration phase of treatment whose dose has been stable for a period of 4 weeks—a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks;

(iv) for a patient whose dose had been stable for a period of at least 4 weeks at the time of the initial application for PBS-subsidy—a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment.

(n) for HSD pharmaceutical benefits that have the drug romiplostim, for the first period of continuing treatment or re-initiation of interrupted PBS subsidised treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with Romiplostim during the initial period of PBS-subsidised treatment—a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks treatment.

(o) for HSD pharmaceutical benefits that have the drug romiplostim, for the second and subsequent periods of continuing treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who continues to display a sustained platelet response to treatment with Romiplostim—a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment.

(p) for HSD pharmaceutical benefits that have the drug omalizumab, for initial treatment of uncontrolled severe allergic asthma—a quantity of units that are sufficient to provide for 28 weeks treatment;

(q) for HSD pharmaceutical benefits that have the drug omalizumab, for initial PBS-subsidised treatment of uncontrolled severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)—a quantity of units that are sufficient to provide for 24 weeks treatment;

(r) for HSD pharmaceutical benefits that have the drug omalizumab, for continuing treatment—a quantity of units that are sufficient to provide for 24 weeks treatment.

(s) for HSD pharmaceutical benefits that have the drug eltrombopag, for initial PBS-subsidised treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP):

(i) with the form Tablet 25 mg (as olamine)—up to 28 tablets;

(ii) with the form Tablet 50 mg (as olamine)—up to 28 tablets;

—a quantity of units that are sufficient for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks.

(t) for HSD pharmaceutical benefits that have the drug eltrombopag, for initial PBS-subsidised treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with Eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment in the circumstances can be demonstrated to have been met at the time his or her treatment with Eltrombopag was commenced):

(i) with the form Tablet 25 mg (as olamine)—up to 28 tablets;

(ii) with the form Tablet 50 mg (as olamine)—up to 28 tablets;

—a quantity of units that are sufficient for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks.

(u) for HSD pharmaceutical benefits that have the drug eltrombopag, for the first period of continuing treatment or re-initiation of interrupted PBS subsidised treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with Eltrombopag during the initial period of PBS-subsidised treatment:

(i) with the form Tablet 25 mg (as olamine)—up to 28 tablets;

(ii) with the form Tablet 50 mg (as olamine)—up to 28 tablets;

—a quantity of units that are sufficient for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks.

(v) for HSD pharmaceutical benefits that have the drug eltrombopag, for the second and subsequent periods of continuing treatment as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who continues to display a sustained platelet response to treatment with Eltrombopag:

(i) with the form Tablet 25 mg (as olamine)—up to 28 tablets;

(ii) with the form Tablet 50 mg (as olamine)—up to 28 tablets;

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—a quantity of units that are sufficient for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks.

(w) for HSD pharmaceutical benefits that have the drug tocilizumab, for the treatment of patients with severe active systemic juvenile idiopathic arthritis—a quantity of units sufficient for up to 1 month of treatment with the drug.

25 HSD pharmaceutical benefits that have CAR drugs—repeat exceptions

(1) An eligible medical practitioner may authorise the repeat supply of an HSD pharmaceutical benefit that has a CAR drug mentioned in subsection (2) only in accordance with the limitations mentioned in subsection (2) for the drug.

(2) The drugs and limitations are as follows:

(a) for bosentan:

(i) if the prescription is for the balance of a 6 month course of initial treatment for a patient who has been issued with an authority prescription for the first month of the 6 month course—up to 4 repeat supplies; or

(ii) if the prescription is for continuing treatment of a patient who has achieved a response to his or her most recent course of PBS-subsidised treatment—up to 5 repeat supplies;

(b) for etanercept:

(i) for the initial treatment of severe polyarticular course juvenile chronic arthritis—up to 3 repeat supplies; or

(ii) for the continuing treatment of severe polyarticular course juvenile chronic arthritis—up to 5 repeat supplies;

(c) for infliximab, for the treatment of an adult with severe active rheumatoid arthritis:

(i) if the circumstances permit a course of up to a maximum of 22 weeks of treatment to be authorised—up to 3 repeat supplies; or

(ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 2 repeat supplies;

(d) for infliximab, for the treatment of an adult with severe active psoriatic arthritis:

(i) if the circumstances permit a course of up to a maximum of 22 weeks of treatment to be authorised—up to 3 repeat supplies; or

(ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 2 repeat supplies;

(e) for infliximab, for the treatment of an adult with active ankylosing spondylitis—up to 3 repeat supplies;

(f) for infliximab, for the treatment of a patient with refractory Crohn disease or fistulating Crohn disease—up to 2 repeat supplies;

(g) for infliximab, for the treatment of an adult with severe chronic plaque psoriasis:

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(i) if the circumstances permit a course of up to a maximum of 22 weeks of treatment to be authorised—up to 3 repeat supplies; or

(ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 2 repeat supplies;

(h) for abatacept, for the treatment of an adult with severe active rheumatoid arthritis:

(i) if the circumstances permit a course of up to a maximum of 16 weeks of treatment to be authorised—up to 4 repeat supplies; or

(ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 5 repeat supplies;

(i) for rituximab—1 repeat supply;

(j) for ambrisentan:

(i) for the initial PBS-subsidised treatment of a patient who was receiving non-PBS-subsidised treatment with ambrisentan for less than 6 months before 1 December 2009—sufficient repeat supplies to allow the patient to complete a period of combined PBS-subsidised and non-PBS-subsidised therapy of up to 6 months duration in total; or

(ii) if subparagraph (i) does not apply—up to 5 repeat supplies;

(k) for lenalidomide, for the treatment of a patient with multiple myeloma—up to 2 repeat supplies;

(l) for lenalidomide, for the treatment of a patient with myelodysplastic syndrome—up to 3 repeat supplies;

(m) for epoprostenol, iloprost, sildenafil, or tadalafil—up to 5 repeat supplies;

(n) for tocilizumab, for the treatment of adults with severe active rheumatoid arthritis:

(i) if the circumstances permit a course of up to a maximum of 16 weeks of treatment to be authorised—up to 3 repeat supplies;

(ii) If the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 5 repeat supplies;

(o) for adalimumab for the treatment of a patient with juvenile idiopathic arthritis:

(i) if the circumstances permit a course of up to a maximum of 16 weeks of treatment to be authorised—up to 3 repeat supplies;

(ii) if the circumstances permit a course of up to a maximum of 24 weeks treatment to be authorised—up to 5 repeat supplies;

(p) for azacitidine:

(i) for initial treatment—up to 2 repeat supplies;

(ii) for continuing treatment—up to 5 repeat supplies.

(q) for romiplostim for initial treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP):

(i) at the time of the initial written authority application—1 repeat supply;

(ii) during the initial period of dose titration—1 repeat supply;

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(iii) for a patient whose dose has been stable for a period of 4 weeks—up to 4 repeat supplies.

(r) for romiplostim for initial PBS-subsidised treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with Romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment in the circumstances can be demonstrated to have been met at the time his or her treatment with romplostin was commenced:

(i) at the time of the initial written authority application—1 repeat supply;

(ii) during the initial period of dose titration—1 repeat supply;

(iii) for a patient in the titration phase of treatment whose dose has been stable for a period of 4 weeks—up to 4 repeat supplies;

(iv) for a patient whose dose had been stable for a period of at least 4 weeks at the time of the initial application for PBS-subsidy—up to 5 repeat supplies.

(s) for romiplostim for the first period of continuing treatment or re-initiation of interrupted PBS-subsidised treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpure (ITP) who has displayed a sustained platelet response to treatment with Romiplostim during the initial period of PBS-subsidised treatment:

(i) at the time of the initial written authority application—up to 5 repeat supplies;

(ii) where less than 5 repeat supplies are requested in the initial written authority application—sufficient repeat supplies to complete a maximum of 24 weeks treatment.

(t) for romiplostim for the second and subsequent periods of continuing treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpure (ITP) who continues to display a sustained platelet response to treatment with Romiplostim—up to 5 repeat supplies.

(u) for omalizumab—where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the authority application—sufficient repeat supplies to complete 24 weeks of treatment.

(v) for omalizumab—where at least 24 weeks treatment was requested at the time of the application—0 repeat supplies.

(w) for eltrombopag for initial treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP):

(i) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 5 repeat supplies.

(x) for eltrombopag for initial PBS-subsidised treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor

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agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment in the circumstances can be demonstrated to have been met at the time his or her treatment with eltrombopag was commenced:

(i) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 5 repeat supplies.

(y) for eltrombopag for the first period of continuing treatment or re-initiation of interrupted PBS-subsidised treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpure (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment:

(i) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 5 repeat supplies;

(ii) where less than 5 repeat supplies are requested in the initial written authority application—sufficient repeat supplies to complete a maximum of 24 weeks treatment.

(z) for eltrombopag for the second and subsequent periods of continuing treatment of severe thrombocytopenia as the sole PBS-subsidised thrombopoetin receptor agonist (TRA) in an adult with severe chronic immune (idiopathic) thrombocytopenic purpure (ITP) who continues to display a sustained platelet response to treatment with eltrombopag—up to 5 repeat supplies.

(za) for tocilizumab, for the treatment of patients with severe active systemic juvenile idiopathic arthritis:

(i) if the circumstances permit a course of up to a maximum of 16 weeks of treatment to be authorised—up to 3 repeat supplies;

(ii) If the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised—up to 5 repeat supplies.

(3) In this section, ***circumstances*** means circumstances mentioned in Schedule 3 for the circumstances code mentioned in the column in Schedule 1 headed 'Circumstances' for the HSD pharmaceutical benefit that has the drug.

26 Application of regulation 13 in relation to CAR drugs

Regulation 13 of the Regulations does not apply in relation to a prescription for an HSD pharmaceutical benefit that has a CAR drug supplied under this Special Arrangement.

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Part 4—Claiming procedures and payment amounts

Division 2—Modified section 99AAA claims by approved public hospitals

Subdivision 1—General requirements

30 How claims to be made—modified section 99AAA claiming

An approved hospital authority for a public hospital may make a claim for payment for the supply of an HSD pharmaceutical benefit in accordance with the rules made by the Minister under subsection 99AAA(8) of the Act, as modified by this Division.

Note 1: An approved hospital authority for a public hospital that may make a modified section 99AAA claim may choose instead to make the claim in accordance with the rules made by the Minister under subsection 99AAA(8) of the Act.

31 Limit on number of prescriptions in one claim

The claim for payment must not contain more than 3 500 prescriptions.

Subdivision 3—Payment of claims

35 Payments to suppliers that are approved hospital authorities for public hospitals

(1) An approved hospital authority for a public hospital is entitled to be paid the amount, if any, by which the dispensed price for the supply of the HSD pharmaceutical benefit exceeds the amount that the approved hospital authority was entitled to charge under subsection 46(2).

(2) The dispensed price is to be worked out in accordance with Division 1 of Part 5.

(3) No mark ups may be added to the cost of an HSD pharmaceutical benefit for which payment is claimed under this Division.

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Division 3—Payments to suppliers of HSD pharmaceutical benefits that are approved hospital authorities for private hospitals or approved pharmacists or approved medical practitioners

36 Payments to certain suppliers of HSD pharmaceutical benefits

(1) An approved hospital authority for a private hospital is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for its supply of the HSD pharmaceutical benefit is greater than the amount that the approved hospital authority was entitled to charge under subsection 46(2).

(2) An approved pharmacist or an approved medical practitioner is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of an HSD pharmaceutical benefit is greater than the amount that the approved pharmacist or approved medical practitioner was entitled to charge under subsection 47(2).

(3) The dispensed price for the supply of an HSD pharmaceutical benefit by an approved hospital authority for a private hospital or by an approved pharmacist or by an approved medical practitioner is to be worked out under Division 2 of Part 5.

Note: An approved hospital authority for a private hospital or an approved pharmacist may make claims for payment in accordance with rules made by the Minister under subsection 99AAA(8) of the Act—see section 99AAA(2) of the Act.

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Part 5—Dispensed price

Division 1—Dispensed price for supply of an HSD pharmaceutical benefit by a hospital authority for a public hospital

37 The dispensed price—supply by public hospital

Subject to section 43, the dispensed price for the supply of an HSD pharmaceutical benefit, by a hospital authority for a public hospital, is as follows:

(a) if the quantity of the HSD pharmaceutical benefit that is ordered and supplied is equal to a multiple of a pack quantity of the benefit—the sum of the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity;

(b) if the quantity of the HSD pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit—the amount calculated in accordance with section 38;

(c) if the quantity of the HSD pharmaceutical benefit that is ordered and supplied is more than a multiple of a pack quantity of the benefit—the sum of:

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

(ii) the amount calculated in accordance with section 38 for the remainder of the quantity supplied that is less than a pack quantity.

38 Where quantity is less than a pack quantity

If the quantity of an HSD pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit (a ***broken quantity***), the amount mentioned in paragraph 37(b) and subparagraph 37(c)(ii) is to be calculated by:

(a) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and

(b) applying that percentage to the approved ex-manufacturer price or proportional ex-manufacturer price for the pack quantity.

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Division 2—Dispensed price for supply of HSD pharmaceutical benefit by an approved hospital authority for a private hospital or by an approved pharmacist or approved medical practitioner

39 The dispensed price—supply by an approved hospital authority for a private hospital or by an approved pharmacist or approved medical practitioner

(1) The ***dispensed price*** for the supply of an HSD pharmaceutical benefit by an approved hospital authority for a private hospital, or by an approved pharmacist, or by an approved medical practitioner, is as follows:

(a) if the quantity of the HSD pharmaceutical benefit that is ordered and supplied is equal to a multiple of a pack quantity, the sum of:

(i) the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity, plus the mark-up mentioned in section 40, taken to the nearest cent, with one half cent being rounded up to 1 cent; and

(ii) either:

(A) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the HSD pharmaceutical benefit; or

(B) if the HSD pharmaceutical benefit has a drug mentioned in subsection (2) in the form mentioned in that subsection for the drug—the extemporaneously-prepared dispensing fee mentioned in the the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the HSD pharmaceutical benefit; or

(b) if a quantity of the HSD pharmaceutical benefit that is ordered and supplied is less than a pack quantity, the sum of:

(i) the amount calculated in accordance with section 41; and

(ii) either:

(A) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the HSD pharmaceutical benefit; or

(B) if the HSD pharmaceutical benefit has a drug mentioned in subsection (2) in the form mentioned in that subsection for the drug—the extemporaneously-prepared dispensing fee mentioned in the the determination made under

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paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the HSD pharmaceutical benefit; or

(c) if a quantity of the HSD pharmaceutical benefit that is ordered and supplied is more than a multiple of a pack quantity, the sum of:

(i) for each pack quantity, the approved ex-manufacturer price or the proportional ex-manufacturer price for the pack quantity, plus the mark-up mentioned in section 40, taken to the nearest cent, with one half cent being counted as 1 cent; and

(ii) the amount calculated in accordance with section 41 for the remainder of the quantity supplied that is less than a pack quantity; and

(iii) either:

(A) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the HSD pharmaceutical benefit; or

(B) if the HSD pharmaceutical benefit has the drug mentioned in subsection (2) in the form mentioned in that subsection for the drug—the extemporaneously-prepared dispensing fee set out in the the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the HSD pharmaceutical benefit.

(2) For sub-subparagraphs (1)(a)(ii)(B), (1)(b)(ii)(B) and (1)(c)(iii)(B), the drugs and the forms for the drugs are as follows:

(a) mycophenolic acid as a powder for oral suspension containing mycophenolate mofetil 1g per 5 mL, 165mL;

(c) valganciclovir as a powder for oral solution 50mg (as hydrocholoride) per mL, 100 mL.

40 Mark-up

For subparagraphs 39(1)(a)(i) and 39(1)(c)(i) and paragraph 41(a), the mark-up for a pack quantity of a ready-prepared pharmaceutical benefit is:

(a) if the pack quantity for which a mark-up is to be calculated under this section is equal to a maximum quantity of the HSD pharmaceutical benefit, the mark-up is the amount mentioned in the table below for the approved ex-manufacturer price (AEMP) or proportional ex-manufacturer price (PEMP) for that quantity.

Item	AEMP or PEMP for Maximum Quantity	Mark-up for Maximum Quantity
1	< $40	10% of AEMP or PEMP
2	≥ $40, ≤ $100	$4.00
3	> $100, ≤ $1,000	4% of AEMP or PEMP

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Item	AEMP or PEMP for Maximum Quantity	Mark-up for Maximum Quantity
4	> $1,000	$40.00

(b) if the pack quantity for which a mark-up is to be calculated under this section is not equal to a maximum quantity of the HSD pharmaceutical benefit, the mark-up is worked out as follows:

(i) if the mark-up that would apply to the maximum quantity is shown in the table in paragraph (a) as a monetary amount—the mark-up for the pack quantity is that monetary amount reduced proportionately for the relative quantities; and

(ii) if the mark-up that would apply to the maximum quantity is shown in the table in paragraph (a) as a percentage of AEMP or PEMP—the mark-up for the pack quantity is that percentage of the AEMP or PEMP for the pack quantity.

41 Where quantity is less than a pack quantity

If the quantity of an HSD pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit (a broken quantity), the amount mentioned in subparagraph 39(b)(i) and 39(c)(ii) is to be calculated by:

(a) adding the mark-up mentioned in section 40 to the approved ex-manufacturer price or the proportional ex-manufacturer price for the pack quantity, taking the result to the nearest cent, with one half cent being counted as 1 cent; and

(b) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and

(c) applying the percentage worked out under subparagraph (b) to the amount worked out under subparagraph (a).

42 Dispensing fee

If an eligible medical practitioner, instead of directing a repeated supply of an HSD pharmaceutical benefit, directs the supply on one occasion of a quantity or number of units of the drug, not exceeding the total quantity or number of units that could be prescribed if the eligible medical practitioner directed a repeated supply, the dispensed price for the supply of the HSD pharmaceutical benefit will include only one dispensing fee.

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Division 3—Dispensed price—other matters

44 Rounding up of dispensed price

The dispensed price for the supply of an HSD pharmaceutical benefit will in each case be taken to the nearest cent, one half cent being counted as one cent.

Part 6—Patient contributions

46 Patient contributions in relation to approved hospital authorities

(1) This section applies to an approved hospital authority for a public hospital or a private hospital that supplies an HSD pharmaceutical benefit.

(2) The approved hospital authority may charge the patient an amount equivalent to the amount that may be charged under section 87 of the Act for the supply of a pharmaceutical benefit to the patient.

(3) For section 87 of the Act, the amount that is equal to the special patient contribution for the supply of an HSD pharmaceutical benefit that is a brand of a pharmaceutical item is the amount mentioned in section 48 if the HSD pharmaceutical benefit is mentioned in Schedule 4.

47 Patient contributions for claims by approved pharmacists or approved medical practitioners

(1) This section applies if an approved pharmacists or an approved medical practitioner supplies an HSD pharmaceutical benefit to an eligible patient and makes a claim for payment.

(2) The approved pharmacist or the approved medical practitioner may charge the patient an amount equivalent to the amount that may be charged under section 87 of the Act for the supply of a pharmaceutical benefit to the patient.

(3) For section 87 of the Act, the amount that is equal to the special patient contribution for the supply of an HSD pharmaceutical benefit that is a brand of a pharmaceutical item is the amount mentioned in section 48 if the HSD pharmaceutical benefit is mentioned in Schedule 4.

48 Additional patient contributions

For subsections 46(3) and 47(3), the amount is the amount that is the difference between:

(a) the price that would have been the dispensed price for the quantity of the HSD pharmaceutical benefit supplied if that dispensed price had been based on the claimed price mentioned for the benefit in the column in Schedule 4 headed ‘Claimed Price’; and

(b) the dispensed price for that quantity of the HSD pharmaceutical benefit.

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Part 7—Miscellaneous

49 Compliance and audit arrangements

(1) If an approved supplier supplies HSD pharmaceutical benefits under this Special Arrangement, the approved supplier that supplies the HSD pharmaceutical benefits must keep adequate, secure and auditable records of all supplied HSD pharmaceutical benefits for which a claim is made.

(2) The records must be kept in systems that are able to be audited by the Chief Executive Medicare on reasonable notice being given to the approved supplier.

50 PBS Safety Net

(2) An amount paid by a person because of a charge made by an approved hospital authority under subsection 46(2) counts towards the person's PBS safety net if it is equivalent to the amount chargeable under subsection 87(5) of the Act for the supply of the HSD pharmaceutical benefit less the amount chargeable under that subsection because of subsection 87(2A) of the Act.

(3) An amount paid by a person because of a charge made by an approved pharmacist or approved medical practitioner under subsection 47(2) counts towards the person's PBS safety net, other than an amount equivalent to the amount chargeable under subsection 87(2A) of the Act for the supply of the HSD pharmaceutical benefit to the person.

Note: Division 1A of Part VII of the Act contains provisions about safety net concession cards.

51 Application of Act and Part VII instruments to approved suppliers and prescriptions etc

For the application of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act:

(a) a reference in the Act or other instrument to an approved supplier or an approved hospital authority includes a reference to a hospital authority approved under:
  (i) subsection 52(2) of this Special Arrangement; or
  (ii) subsection 52(2) of the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010 (PB 63 of 2010)*; and

(b) a reference in the Act or other instrument to a number allotted to an approval under regulation 8A includes a reference to a number allotted to an approval under:
  (i) subsection 52(3) of this Special Arrangement; and

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(ii) subsection 52(3) of the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010 (PB 63 of 2010)*; and

(c) a medication chart prescription may be written for an eligible patient receiving treatment from a hospital; and

(f) the rules made under subsection 98AC(4) of the Act apply to a supply of a HSD pharmaceutical benefit by an approved pharmacist, approved medical practitioner or approved hospital authority for a hospital under this Special Arrangement as if the definition of under co-payment data appearing in those rules was replaced with the definition of under co-payment data in section 4 of this Special Arrangement.

Note 1: Section 84 of the Act defines ***approved hospital authority*** and ***approved supplier*** for Part VII of the Act.

Note 2: The rules made by the Minister under subsection 99AAA(8) of the Act are instruments made under Part VII of the Act.

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Part 8—Approval of certain hospital authorities

52 Approval of certain public hospital authorities

(1) A hospital authority for a public hospital, that must not be approved under section 94 of the Act because of subsection 94(5) of the Act, may apply, in writing, to the Chief Executive Medicare for approval under this Part for the purpose of its supplying HSD pharmaceutical benefits under this Special Arrangement to eligible patients receiving treatment at or from the hospital of which it is the governing body.

(2) The Chief Executive Medicare may, in writing, approve the hospital authority for this Special Arrangement.

(3) If the Chief Executive Medicare approves the hospital authority, he or she may allot a number to the approval.

(4) A number allotted to a hospital authority under either of the following provisions is to be treated as having been allotted by the Secretary under subregulation 8A (1) of the Regulations:

(a) subsection (3) of this section;

(b) subsection 52(3) of the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010*.

(5) The approval may be subject to any conditions the Chief Executive Medicare determines.

(6) The Chief Executive Medicare must, in writing, notify the hospital authority of his or her decision on the hospital authority's application.

(7) The Chief Executive Medicare may, at any time, by notice in writing to the hospital authority, vary, suspend or revoke the approval.

Note: An approval under this Part may only be made for a hospital authority for a public hospital and does not constitute an approval under section 94 of the Act.

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Part 9—Transitional arrangements

53 Approvals of certain hospital authorities of public hospitals

Despite the revocation of the *National Health (Highly specialised drugs program for public hospitals) Special Arrangements Instrument 2010 (PB 63 of 2010)*, an approval that was in force under subsection 52(2) of that Instrument immediately before the commencement of this section continues in force under this Special Arrangement as if it were an approval under subsection 52(2) of this Special Arrangement.

54 Transitional arrangements for existing public hospital medication chart prescribing and paperless claiming

(1) An eligible medical practitioner at a public hospital may prescribe a HSD pharmaceutical benefit that has a non-CAR drug under this Special Arrangement, before 1 April 2017, by following the requirements for prescribing from a medication chart in the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* as in force immediately before 1 April 2015.

(2) An approved hospital authority for a public hospital can supply a HSD pharmaceutical benefit prescribed under subsection (1).

(3) The requirements for prescribing, supplying and claiming from a medication chart set out in the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* as in force immediately before 1 April 2015, continue to apply in relation to a medication chart prepared under subsection (1).

(4) However, this section does not apply if the public hospital referred to in subsections (1) and (2) is a listed approved hospital under regulation 59 of the Regulations.

(5) However, if this section applies, the supply certification referred to in subrule 5(1A) of the rules made under subsections 98AC(4) and 99AAA(8) of the Act is allowed, and then required, as indicated in transitional rule 12 of those rules.

55 Transitional arrangements for existing non-medication chart public hospital paperless claiming

(1) An approved hospital authority for a public hospital may supply a HSD pharmaceutical benefit that has a non-CAR drug before 1 April 2017, from a prescription other than a medication chart, in accordance with Part 4, Division 2, Subdivision 2 of the *National Health (Highly specialised drugs program for*

hospitals) Special Arrangement 2010 as in force immediately before 1 April 2015.

(2) However, if this section applies, the supply certification referred to in subrule 5(1A) of the rules made under subsections 98AC(4) and 99AAA(8) of the Act is allowed, and then required, as indicated in transitional rule 12 of those rules.

56 Transitional arrangements for repeat prescriptions

(1) Where an authorised prescriber has issued a repeat prescription prior to 1 July 2015, the new arrangements apply to the supply of the repeat pharmaceutical benefits.

(2) In this section ***new arrangements*** mean the *National Health (Highly specialised drugs program) Special Arrangement 2010* as in force on 1 July 2015.

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Schedule 1—Pharmaceutical benefits covered by this Special Arrangement and related information

(sections 5, 7, 8, 9, 10, 14, 15, 16 and 25)

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Abacavir	Tablet 300 mg (as sulfate)	Oral	Ziagen	VI	EMP	C4454 C4512		120	5	D
	Oral solution 20 mg (as sulfate) per mL, 240 mL	Oral	Ziagen	VI	EMP	C4454 C4512		8	5	D
Abacavir with Lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	Kivexa	VI	EMP	C4527 C4528		60	5	D
Abacavir with Lamivudine and Zidovudine	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	Oral	Trizivir	VI	EMP	C4480 C4495		120	5	D
Abatacept	Powder for I.V. infusion 250 mg	Injection	Orencia	BQ	EMP	C5456 C5493 C5523 C4695 C4734		See Note 1	See Note 2	PB

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Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	EMP	C4464 C4465 C4491 C4500 C4546		See Note 1	See Note 2	PB
	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	EMP	C4464 C4465 C4491 C4500 C4546		See Note 1	See Note 2	C
	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	EMP	C4464 C4465 C4491 C4500 C4546		See Note 1	See Note 2	C
Adefovir	Tablet containing adefovir dipivoxil 10 mg	Oral	APO-Adefovir	TX	EMP	C4490 C4510		60	5	D
			Hepsera	GI	EMP	C4490 C4510		60	5	D
Alemtuzumab	Solution concentrate for I.V. infusion 12 mg in 1.2 mL	Injection	Lemtrada	GZ	EMP	C4829 C4834 C4838 C4850	P4829 P4850	3	0	D
			Lemtrada	GZ	EMP	C4829 C4834 C4838 C4850	P4834 P4838	5	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Ambrisentan	Tablet 5 mg	Oral	Volibris	GK	EMP	C6065 C6066 C6078 C6089 C6102 C6117		See Note 1	See Note 2	D
	Tablet 10 mg	Oral	Volibris	GK	EMP	C4619 C4631 C4633 C4634 C4639		See Note 1	See Note 2	D
Anakinra	Injection 100 mg in 0.67 mL single use pre-filled syringe	Injection	Kineret	FK	EMP	C5450		28	5	D
Apomorphine	Injection containing apomorphine hydrochloride 10 mg in 1 mL	Injection	Apomine	HH	EMP	C4833 C4860		360	5	D
	Injection containing apomorphine hydrochloride 20 mg in 2 mL	Injection	Movapo	TD	EMP	C4833 C4860		360	5	D
	Injection containing apomorphine hydrochloride 50 mg in 5 mL	Injection	Movapo	TD	EMP	C4833 C4860		180	5	D
Atazanavir	Capsule 150 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C4454 C4512		120	5	D
	Capsule 200 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C4454 C4512		120	5	D

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 300 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C4454 C4512		60	5	D
Atazanavir with cobicistat	Tablet containing 300 mg atazanavir and 150 mg cobicistat	Oral	Evotaz	BQ	EMP	C4454 C4512		60	5	D
Azacitidine	Powder for injection 100 mg	Injection	Azadine	RZ	EMP	C6132 C6143 C6144 C6177 C6186 C6199	P6132 P6143 P6177	See Note 1	See Note 2	D
			Vidaza	CJ	EMP	C6132 C6143 C6144 C6177 C6186 C6199	P6132 P6143 P6177	See Note 1	See Note 2	D
			Azadine	RZ	EMP	C6132 C6143 C6144 C6177 C6186 C6199	P6144 P6186 P6199	See Note 1	See Note 2	D
			Vidaza	CJ	EMP	C6132 C6143 C6144 C6177 C6186 C6199	P6144 P6186 P6199	See Note 1	See Note 2	D
Azithromycin	Tablet 600 mg (as dihydrate)	Oral	Zithromax	PF	EMP	C1299 C3317		16	5	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Baclofen	Intrathecal injection 10 mg in 5 mL	Injection	Bacthecal	DZ	EMP	C5985 C5990 C6000 C6003 C6025 C6051 C6052 C6054		10	0	PB
			Lioresal Intrathecal	NV	EMP	C5985 C5990 C6000 C6003 C6025 C6051 C6052 C6054		10	0	PB
Boceprevir	Capsule 200 mg	Oral	Victrelis	MK	EMP	C4182 C4196 C4202 C4205		336	10	D
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Tracleer	AT	EMP	C4628 C6063 C6064 C6065 C6066 C6089 C6107		See Note 1	See Note 2	D
	Tablet 125 mg (as monohydrate)	Oral	Tracleer	AT	EMP	C6063 C6064 C6065 C6066 C6089 C6107		See Note 1	See Note 2	D
Clarithromycin	Tablet 500 mg	Oral	APO Clarithromycin	TX	EMP	C5873 C5874		100	2	D

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Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Clozapine	Tablet 25 mg	Oral	Clopine 25	HH	EMP	C4998 C5001 C5015		200	0	D
			Clozaril 25	NV	EMP	C4998 C5001 C5015		200	0	D
	Tablet 50 mg	Oral	Clopine 50	HH	EMP	C4998 C5001 C5015		200	0	D
	Tablet 100 mg	Oral	Clopine 100	HH	EMP	C4998 C5001 C5015		200	0	D
			Clozaril 100	NV	EMP	C4998 C5001 C5015		200	0	D
	Tablet 200 mg	Oral	Clopine 200	HH	EMP	C4998 C5001 C5015		200	0	D
	Oral liquid 50 mg per mL, 100 mL	Oral	Clopine Suspension	HH	EMP	C4998 C5001 C5015		1	0	D
Cyclosporin	Capsule 10 mg	Oral	Neoral 10	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 25 mg	Oral	Cyclosporin Sandoz	SZ	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
			Neoral 25	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
	Capsule 50 mg	Oral	Cyclosporin Sandoz	SZ	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
			Neoral 50	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C

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Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 100 mg	Oral	Cyclosporin Sandoz	SZ	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
			Neoral 100	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
	Oral liquid 100 mg per mL, 50 mL	Oral	Neoral	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		4	5	C
	Solution concentrate for I.V. infusion 50 mg in 1 mL	Injection	Sandimmun	NV	EMP	C1504 C3333		10	0	PB
Daclatasvir	Tablet 30 mg	Oral	Daklinza	BQ	EMP	C5969 C5972	P5969	28	2	
					EMP	C5969 C5972	P5972	28	5	
	Tablet 60 mg	Oral	Daklinza	BQ	EMP	C5969 C5972	P5969	28	2	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					EMP	C5969 C5972	P5972	28	5	
Darbepoetin Alfa	Injection 10 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 20 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 20 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C6260 C6294		8	5	D
	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 40 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 40 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C6260 C6294		8	5	D
	Injection 50 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 60 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 60 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C6260 C6294		8	5	D

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 80 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 80 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C6260 C6294		8	5	D
	Injection 100 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 100 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C6260 C6294		8	5	D
	Injection 150 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C6260 C6294		8	5	D
	Injection 150 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C6260 C6294		8	5	D
Darunavir	Tablet 150 mg (as ethanolate)	Oral	Prezista	JC	EMP	C5094		240	5	D
	Tablet 600 mg (as ethanolate)	Oral	Prezista	JC	EMP	C5094		120	5	D
	Tablet 800mg (as ethanolate)	Oral	Prezista	JC	EMP	C4313		60	5	D
Deferasirox	Tablet, dispersible, 125 mg	Oral	Exjade	NV	EMP	C3828 C3829		168	5	D
	Tablet, dispersible, 250 mg	Oral	Exjade	NV	EMP	C3828 C3829		168	5	D
	Tablet, dispersible, 500 mg	Oral	Exjade	NV	EMP	C3828 C3829		168	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Deferiprone	Tablet 500 mg	Oral	Ferriprox	TX	EMP	C1911 C1912 C3338 C3339		600	5	D
	Oral solution 100 mg per mL, 250 mL	Oral	Ferriprox	TX	EMP	C1911 C1912 C3338 C3339		5	5	D
Desferrioxamine	Powder for injection containing desferrioxamine mesylate 500 mg	Injection	Hospira Pty Limited	HH	EMP	C1085 C3340		400	5	D
			Hospira Pty Limited	HH	EMP	C1085 C3340		400	5	D
	Powder for injection containing desferrioxamine mesylate 2 g	Injection	Hospira Pty Limited	HH	EMP	C1085 C3340		60	5	D
Didanosine	Capsule 125 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C4454 C4512		60	5	D
	Capsule 200 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C4454 C4512		60	5	D
	Capsule 250 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C4454 C4512		60	5	D
	Capsule 400 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C4454 C4512		60	5	D
Dolutegravir	Tablet 50mg (as sodium)	Oral	Tivicay	VI	EMP	C4454 C4512		60	5	D

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Dolutegravir with abacavir and lamivudine	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	Oral	Triumeq	VI	EMP	C4480 C4495		60	5	D
Dornase Alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation	Pulmozyme	RO	EMP	C5634 C5635 C5715 C5740 C5768 C5800		60	5	D
Doxorubicin - Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	JC	EMP	C6233 C6234 C6264 C6274		4	5	D
			Liposomal Doxorubicin SUN	RA	EMP	C6233 C6234 C6264 C6274		4	5	D
Eculizumab	Solution concentrate for I.V. infusion 300 mg in 30 mL	Injection	Soliris	XI	EMP	C5926 C5929 C5930 C5931 C5932 C5933 C5934 C5935	P5933	1	0	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
						C5926 C5929 C5930 C5931 C5932 C5933 C5934 C5935	P5931	1	4	D
						C5926 C5929 C5930 C5931 C5932 C5933 C5934 C5935	P5926 P5929 P5930 P5932 P5934	1	5	D
						C5926 C5929 C5930 C5931 C5932 C5933 C5934 C5935	P5935	1	6	D
Efavirenz	Tablet 200 mg	Oral	Stocrin	MK	EMP	C4454 C4512		180	5	D
	Tablet 600 mg	Oral	Stocrin	MK	EMP	C4454 C4512		60	5	D
	Oral solution 30 mg per mL, 180 mL	Oral	Stocrin	MK	EMP	C4454 C4512		7	5	D
Eltrombopag	Tablet 25 mg (as olamine)	Oral	Revolade	NV	EMP	C3855 C3856 C3857 C3858		See Note 1	See Note 2	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 50 mg (as olamine)	Oral	Revolade	NV	EMP	C3855 C3856 C3857 C3858		See Note 1	See Note 2	D
Emtricitabine	Capsule 200 mg	Oral	Emtriva	GI	EMP	C4454 C4512		60	5	D
Enfuvirtide	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	Injection	Fuzeon	RO	EMP	C5014		2	5	D
Entecavir	Tablet containing entecavir monohydrate 0.5 mg	Oral	Baraclude	BQ	EMP	C4993 C5036		60	5	D
	Tablet containing entecavir monohydrate 1 mg	Oral	Baraclude	BQ	EMP	C5037 C5044		60	5	D
Epoetin Alfa	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 1000	JC	EMP	C6260 C6294		12	5	D
	Injection 2,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 2000	JC	EMP	C6260 C6294		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Eprex 3000	JC	EMP	C6260 C6294		12	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Eprex 4000	JC	EMP	C6260 C6294		12	5	D
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 5000	JC	EMP	C6260 C6294		12	5	D
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Eprex 6000	JC	EMP	C6260 C6294		12	5	D
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Eprex 8000	JC	EMP	C6260 C6294		12	5	D
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Eprex 10000	JC	EMP	C6260 C6294		12	5	D
	Injection 20,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 20,000	JC	EMP	C6260 C6294		12	5	D
	Injection 40,000 units in 1 mL pre-filled syringe	Injection	Eprex 40,000	JC	EMP	C6260 C6294		2	5	D
Epoetin Beta	Injection 2,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C6260 C6294		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C6260 C6294		12	5	D

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 4,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C6260 C6294		12	5	D
	Injection 5,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C6260 C6294		12	5	D
	Injection 6,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C6260 C6294		12	5	D
	Injection 10,000 units in 0.6 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C6260 C6294		12	5	D
Epoetin Lambda	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
	Injection 2,000 units in 1 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Novicrit	SZ	EMP	C6245 C6261		12	5	D
Epoprostenol	Powder for I.V. infusion, 500 micrograms (as sodium) infusion administration set	Injection	Flolan Kit	GK	EMP	C6065 C6066 C6090 C6122 C6123		See Note 1	See Note 2	D
	Powder for I.V. infusion 500 micrograms (as sodium)	Injection	Veletri	AT	EMP	C6065 C6066 C6090 C6122 C6123		See Note 1	See Note 2	D
	Powder for I.V. infusion, 1.5 mg (as sodium) infusion administration set	Injection	Flolan Kit	GK	EMP	C6065 C6066 C6090 C6122 C6123		See Note 1	See Note 2	D
	Powder for I.V. infusion 1.5 mg (as sodium)	Injection	Veletri	AT	EMP	C6065 C6066 C6090 C6122 C6123		See Note 1	See Note 2	

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	EMP	C4459 C4461 C4486 C4487 C4540		See Note 1	See Note 2	C
	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	EMP	C4459 C4461 C4486 C4487 C4540		See Note 1	See Note 2	C
	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	PF	PF	EMP	C4459 C4461 C4486 C4487 C4540		See Note 1	See Note 2	C
Etravirine	Tablet 200 mg	Oral	Intelence	JC	EMP	C5014		120	5	D
Everolimus	Tablet 0.25 mg	Oral	Certican	NV	EMP	C5554 C5555 C5794 C5795		120	5	C
	Tablet 0.5 mg	Oral	Certican	NV	EMP	C5554 C5555 C5794 C5795		120	5	C
	Tablet 0.75 mg	Oral	Certican	NV	EMP	C5554 C5555 C5794 C5795		240	5	C
	Tablet 1 mg	Oral	Certican	NV	EMP	C5554 C5555 C5794 C5795		240	5	C

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Filgrastim	Injection 120 micrograms in 0.2 mL single use pre-filled syringe	Injection	Nivestim	HH	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 300 micrograms in 1 mL	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Neupogen)	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)	Injection	Nivestim	HH	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (TevaGrastim)	Injection	TevaGrastim	TB	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Zarzio)	Injection	Zarzio	SZ	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Neupogen)	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)	Injection	Nivestim	HH	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Zarzio)	Injection	Zarzio	SZ	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 0.8 mL single use pre-filled syringe (TevaGrastim)	Injection	TevaGrastim	AS	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Fosamprenavir	Tablet 700 mg (as calcium)	Oral	Telzir	VI	EMP	C4454 C4512		120	5	D
Foscarnet	I.V. infusion containing foscarnet sodium 24 mg per mL, 250 mL	Injection	Foscavir	IX	EMP	C4973 C4980		6	1	D
Ganciclovir	Powder for I.V. infusion 500 mg (as sodium)	Injection	Cymevene	RO	EMP	C4972 C4990 C4999 C5000 C5025		10	1	D
Ibandronic acid	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	Injection	Bondronat	RO	EMP	C5257 C5291		1	11	PB
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation	Ventavis	BN	EMP	C6065 C6066 C6077 C6089 C6113 C6128		See Note 1	See Note 2	D
Indinavir	Capsule 400 mg (as sulfate)	Oral	Crixivan 400 mg	MK	EMP	C4454 C4512		360	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	HH	EMP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5376 C5377 C5440 C5484 C5485 C5570 C6076 C6082 C6110	P3691 P3693 P3819 P3820 P4603 P4625 P4626 P4627 P4630 P4705 P4718 P4846 P4854 P5077 P5078 P5079 P5084 P5097 P5103 P5109 P5110 P5111 P5112 P5118 P5120 P5149 P5197 P5233 P5234 P5303 P5304 P5376 P5377 P5440 P5484 P5485 P5570 P6076 P6082 P6110	1	0	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Remicade	JC	EMP	C3691 C3693	P3691 P3693	1	0	D
						C3819 C3820	P3819 P3820			
						C4524 C4535	P4603 P4625			
						C4603 C4625	P4626 P4627			
						C4626 C4627	P4630 P4705			
						C4630 C4705	P4718 P4846			
						C4718 C4846	P4854 P5077			
						C4854 C5077	P5078 P5079			
						C5078 C5079	P5084 P5097			
						C5084 C5097	P5103 P5109			
						C5103 C5109	P5110 P5111			
						C5110 C5111	P5112 P5118			
						C5112 C5118	P5120 P5149			
						C5120 C5149	P5197 P5233			
						C5197 C5233	P5234 P5303			
						C5234 C5303	P5304 P5376			
						C5304 C5376	P5377 P5440			
						C5377 C5440	P5484 P5485			
						C5484 C5485	P5570 P6076			
						C5570 C6076	P6082 P6110			
						C6082 C6110				

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Inflectra	HH	EMP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5376 C5377 C5440 C5484 C5485 C5570 C6076 C6082 C6110	P4535	1	1	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Remicade	JC	EMP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5376 C5377 C5440 C5484 C5485 C5570 C6076 C6082 C6110	P4535	1	1	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Inflectra	HH	EMP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5376 C5377 C5440 C5484 C5485 C5570 C6076 C6082 C6110	P4524	5	1	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Remicade	JC	EMP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5376 C5377 C5440 C5484 C5485 C5570 C6076 C6082 C6110	P4524	5	1	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C4993 C5003 C5036 C5042		30	5	C
	Injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C4993 C5003 C5036 C5042		30	5	C
	Injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C4993 C5003 C5036 C5042		30	5	C
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C4993 C5003 C5036 C5042		30	5	C
Interferon Alfa-2b	Solution for injection 10,000,000 I.U. in 1 mL single dose vial	Injection	Intron A	MK	EMP	C4974 C4993 C5003 C5033 C5036 C5042		15	5	PB
	Solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	MK	EMP	C4974 C4993 C5003 C5033 C5036 C5042		2	5	C
	Solution for injection 18,000,000 I.U. in 3 mL single dose vial	Injection	Intron A	MK	EMP	C4974 C4993 C5003 C5033 C5036 C5042		15	5	PB

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Solution for injection 25,000,000 I.U. in 2.5 mL single dose vial	Injection	Intron A	MK	EMP	C4974 C4993 C5003 C5033 C5036 C5042		15	5	PB
	Solution for injection 30,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	MK	EMP	C4974 C4993 C5003 C5033 C5036 C5042		2	5	C
	Solution for injection 60,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	MK	EMP	C4974 C4993 C5003 C5033 C5036 C5042		2	5	PB
Interferon Gamma-1b	Injection 2,000,000 I.U. in 0.5 mL	Injection	Imukin	BY	EMP	C6222 C6286		12	11	D
Ivacaftor	Tablet 150 mg	Oral	Kalydeco	VR	EMP	C5492 C5507 C5531		56	5	D
Lamivudine	Tablet 100 mg	Oral	Zeffix	RW	EMP	C4993 C5036		56	5	D
			Zetlam	AF	EMP	C4993 C5036		56	5	D
	Tablet 150 mg	Oral	3TC	VI	EMP	C4454 C4512		120	5	D
			Lamivudine RBX	RA	EMP	C4454 C4512		120	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Lamivudine Alphapharm	AF	EMP	C4454 C4512		120	5	D
	Tablet 300 mg	Oral	3TC	VI	EMP	C4454 C4512		60	5	D
			Lamivudine RBX	RA	EMP	C4454 C4512		60	5	D
			Lamivudine Alphapharm	AF	EMP	C4454 C4512		60	5	D
	Oral solution 5 mg per mL, 240 mL	Oral	Zeffix	RW	EMP	C4993 C5036		5	5	D
	Oral solution 10 mg per mL, 240 mL	Oral	3TC	VI	EMP	C4454 C4512		8	5	D
Lamivudine with Zidovudine	Tablet 150 mg-300 mg	Oral	Combivir	VI	EMP	C4454 C4512		120	5	D
			Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	AF	EMP	C4454 C4512		120	5	D
Lanreotide	Powder for suspension for injection 30 mg (as acetate) with diluent	Injection	Somatuline LA	IS	EMP	C4559 C4567		2	11	D
	Injection 60 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	EMP	C4569 C4570 C4574 C4575		2	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 90 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	EMP	C4569 C4570 C4574 C4575		2	5	D
	Injection 120 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	EMP	C4569 C4570 C4574 C4575		2	5	D
Lanthanum	Tablet, chewable, 500 mg (as carbonate hydrate)	Oral	Fosrenol	ZI	EMP	C5454 C5530		180	5	C
	Tablet, chewable, 750 mg (as carbonate hydrate)	Oral	Fosrenol	ZI	EMP	C5454 C5530		180	5	C
	Tablet, chewable, 1000 mg (as carbonate hydrate)	Oral	Fosrenol	ZI	EMP	C5454 C5530		180	5	C
Ledipasvir with sofosbuvir	Tablet containing 90 mg ledipasvir with 400 mg sofosbuvir	Oral	Harvoni	GI	EMP	C5944 C5969 C5972	P5944	28	1	
					EMP	C5944 C5969 C5972	P5969	28	2	
					EMP	C5944 C5969 C5972	P5972	28	5	
Lenalidomide	Capsule 5 mg	Oral	Revlimid	CJ	EMP	C4090 C4091 C4282 C4287		See Note 1	See Note 2	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 10 mg	Oral	Revlimid	CJ	EMP	C4090 C4091 C4282 C4287		See Note 1	See Note 2	D
	Capsule 15 mg	Oral	Revlimid	CJ	EMP	C4090 C4091		See Note 1	See Note 2	D
	Capsule 25 mg	Oral	Revlimid	CJ	EMP	C4090 C4091		See Note 1	See Note 2	D
Lenograstim	Powder for injection 13,400,000 I.U. (105 micrograms)	Injection	Granocyte 13	HH	EMP	C1005 C1046 C1051 C1097 C1140 C1168 C1228 C1238 C1240 C1249 C1274 C1324 C1333 C1555 C3392 C3393 C3394 C3395 C3396 C3397 C3398 C3399 C3400 C3401 C3402 C3403 C3404 C3405		20	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for injection 33,600,000 I.U. (263 micrograms)	Injection	Granocyte 34	HH	EMP	C1005 C1046 C1051 C1097 C1140 C1168 C1228 C1238 C1240 C1249 C1274 C1324 C1333 C1555 C3392 C3393 C3394 C3395 C3396 C3397 C3398 C3399 C3400 C3401 C3402 C3403 C3404 C3405		20	11	D
Levodopa with Carbidopa	Intestinal gel 20 mg-5 mg per mL ,100 mL	Intra-intestinal	Duodopa	VE	EMP	C6154 6179		56	5	C
Lopinavir with Ritonavir	Tablet 100 mg-25 mg	Oral	Kaletra	VE	EMP	C4454 C4512		120	5	D
	Tablet 200 mg-50 mg	Oral	Kaletra	VE	EMP	C4454 C4512		240	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	Oral	Kaletra	VE	EMP	C4454 C4512		10	5	D
Macitentan	Tablet 10 mg	Oral	Opsumit	AT	EMP	C6065 C6066 C6074 C6089 C6102 C6115		30	0	D
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth	Bronchitol	XA	EMP	C5658 C5799		4	5	D
Maraviroc	Tablet 150 mg	Oral	Celsentri	VI	EMP	C5008		120	5	D
	Tablet 300 mg	Oral	Celsentri	VI	EMP	C5008		120	5	D
Methoxy polyethylene glycol-epoetin beta	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D
	Injection 50 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D
	Injection 75 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D
	Injection 100 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 120 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D
	Injection 200 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D
	Injection 360 micrograms in 0.6 mL pre-filled syringe	Injection	Mircera	RO	EMP	C6260 C6294		2	5	D
Mycophenolic Acid	Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid	Oral	Myfortic	NV	EMP	C4108 C4146 C4084 C4095		240	5	C
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	Myfortic	NV	EMP	C4108 C4146 C4084 C4095		240	5	C
	Capsule containing mycophenolate mofetil 250 mg	Oral	APO-Mycophenolate	TX	EMP	C5600 C5601 C5626 C5653		600	5	D
			CellCept	RO	EMP	C5600 C5601 C5626 C5653		600	5	D
			Ceptolate	AF	EMP	C5600 C5601 C5626 C5653		600	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Mycophenolate Sandoz	SZ	EMP	C5600 C5601 C5626 C5653		600	5	D
			Pharmacor Mycophenolate 250	CR	EMP	C5600 C5601 C5626 C5653		600	5	D
	Tablet containing mycophenolate mofetil 500 mg	Oral	APO-Mycophenolate	TX	EMP	C5554 C5555 C5794 C5795		300	5	D
			CellCept	RO	EMP	C5554 C5555 C5794 C5795		300	5	D
			Ceptolate	AF	EMP	C5554 C5555 C5794 C5795		300	5	D
			Mycophenolate AN	EA	EMP	C5554 C5555 C5794 C5795		300	5	D
			Mycophenolate Sandoz	SZ	EMP	C5554 C5555 C5794 C5795		300	5	D
			Pharmacor Mycophenolate 500	CR	EMP	C5554 C5555 C5794 C5795		300	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL	Oral	CellCept	RO	EMP	C5554 C5555 C5794 C5795		2	5	C
Natalizumab	Solution concentrate for I.V. infusion 300 mg in 15 mL	Injection	Tysabri	BD	EMP	C5987 C6012 C6043		1	5	D
Nevirapine	Tablet 200 mg	Oral	Nevipin	EA	EMP	C4454 C4512		120	5	D
			Nevirapine Alphapharm	AF	EMP	C4454 C4512		120	5	D
			Nevirapine RBX	RA	EMP	C4454 C4512		120	5	D
			Viramune	BY	EMP	C4454 C4512		120	5	D
	Tablet 400 mg (extended release)	Oral	Viramune XR	BY	EMP	C4454 C4526		60	5	D
	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	Oral	Viramune	BY	EMP	C4454 C4512		10	5	D
Octreotide	Injection 50 micrograms (as acetate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide MaxRx	GQ	EMP	C2622 C2623 C3407 C3408		90	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Octreotide (SUN)	RA	EMP	C2622 C2623 C3407 C3408		90	11	D
			Sandostatin 0.05	NV	EMP	C2622 C2623 C3407 C3408		90	11	D
	Injection 100 micrograms (as acetate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide MaxRx	GQ	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide (SUN)	RA	EMP	C2622 C2623 C3407 C3408		90	11	D
			Sandostatin 0.1	NV	EMP	C2622 C2623 C3407 C3408		90	11	D
	Injection 500 micrograms (as acetate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide MaxRx	GQ	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide (SUN)	RA	EMP	C2622 C2623 C3407 C3408		90	11	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Sandostatin 0.5	NV	EMP	C2622 C2623 C3407 C3408		90	11	D
	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	EMP	C5896 C5899 C5900 C5901 C5906 C5910		2	5	D
	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	EMP	C5896 C5899 C5900 C5901 C5906 C5910		2	5	D
	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	EMP	C5896 C5899 C5900 C5901 C5906 C5910		2	5	D
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Xolair	NV	EMP	C4875 C4879 C4880 C6142		See Note 1	See Note 2	D
	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Xolair	NV	EMP	P4875 P4879 P4880 P4886		See Note 1	See Note 2	D
Pamidronic Acid	Concentrated injection containing disodium pamidronate 15 mg in 5 mL	Injection	Pamisol	HH	EMP	C4430 C4433		4	2	C

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Concentrated injection containing disodium pamidronate 30 mg in 10 mL	Injection	Pamisol	HH	EMP	C4430 C4433		2	2	C
	Concentrated injection containing disodium pamidronate 60 mg in 10 mL	Injection	Pamisol	HH	EMP	C4430 C4433		1	2	C
	Concentrated injection containing disodium pamidronate 90 mg in 10 mL	Injection	Pamisol	HH	EMP	C4430 C4433 C5218 C5291 C5256 C5257		1	11	PB
Paritaprevir with ritonavir with ombitasvir and dasabuvir	Pack containing 56 tablets paritaprevir 75 mg with ritonavir 50 mg with ombitasvir 12.5 mg and 56 tablets dasabuvir 250 mg	Oral	Viekira Pak	VE	EMP	C5969		1	2	D
Paritaprevir with ritonavir with ombitasvir and dasabuvir and ribavirin	Pack containing 56 tablets paritaprevir 75 mg with ritonavir 50 mg with ombitasvir 12.5 mg and 56 tablets dasabuvir 250 mg and 56 tablets ribavirin 600 mg	Oral	Viekira Pak-RBV	VE	EMP	C6130 C6131	P6131	1	2	D
					EMP	C6130 C6131	P6130	1	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Pack containing 56 tablets paritaprevir 75 mg with ritonavir 50 mg with ombitasvir 12.5 mg and 56 tablets dasabuvir 250 mg and 168 tablets ribavirin 200 mg	Oral	Viekira Pak-RBV	VE	EMP	C6130 C6131	P6131	1	2	D
					EMP	C6130 C6131	P6130	1	5	D
Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Neulasta	AN	EMP	C2912 C2917 C2918 C2919 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3362 C3363 C3364 C3365 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834		1	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Peginterferon Alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	EMP	C5004 C5010 C5016 C5067		8	5	D
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	EMP	C5004 C5010 C5016 C5067		8	5	D
Plerixafor	Injection 24 mg in 1.2 mL	Injection	Mozobil	GZ	EMP	C4549 C4550		1	1	D
Pomalidomide	Capsule 3 mg	Oral	Pomalyst	CJ	EMP	C5101 C5102		21	0	D
	Capsule 4 mg	Oral	Pomalyst	CJ	EMP	C5101 C5102		21	0	D
Raltegravir	Tablet 25 mg (as potassium)	Oral	Isentress	MK	EMP	C4274 C4275		360	5	D
	Tablet 100 mg (as potassium)	Oral	Isentress	MK	EMP	C4274 C4275		360	5	D
	Tablet 400 mg (as potassium)	Oral	Isentress	MK	EMP	C4454 C4512		120	5	D
Ribavirin	Tablet 400 mg	Oral	Ibavyr	IX	EMP	C5957 C5958	P5957	28	2	
					EMP	C5957 C5958	P5958	28	5	
	Tablet 600 mg	Oral	Ibavyr	IX	EMP	C5957 C5958	P5957	28	2	
					EMP	C5957 C5958	P5958	28	5	
Ribavirin and peginterferon alfa-2a	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207 C5956	P5956	1	2	D
					EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207 C5956	P4184 P4185 P4187 P4188 P4193 P4197 P4206 P4207	2	5	D
	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D
	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207 C5956	P5956	1	2	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207 C5956	P4184 P4185 P4187 P4188 P4193 P4197 P4206 P4207	2	5	D
Ribavirin and Peginterferon Alfa-2b	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4189 C4192 C4193 C4197 C4198 C4199 C4200 C4203 C4206 C4207 C4208 C4209		2	5	D
	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4189 C4192 C4193 C4197 C4198 C4199 C4200 C4203 C4206 C4207 C4208 C4209		2	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D
	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4189 C4192 C4193 C4197 C4198 C4199 C4200 C4203 C4206 C4207 C4208 C4209		2	5	D
	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D
	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D
	Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	MK	EMP	C4184 C4185 C4187 C4188 C4193 C4197 C4206 C4207		2	5	D
Rifabutin	Capsule 150 mg	Oral	Mycobutin	PF	EMP	C1299 C1435 C3317 C3415		120	5	D
Rilpivirine	Tablet 25 mg (as hydrochloride)	Oral	Edurant	JC	EMP	C4454 C4512		60	5	D
Ritonavir	Tablet 100 mg	Oral	Norvir	VE	EMP	C4454 C4512		720	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	Oral	Norvir	VE	EMP	C4454 C4512		10	5	D
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Mabthera	RO	EMP	C5821 C5864 C5872 C5895		See Note 1	See Note 2	D
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	RO	EMP	C5821 C5864 C5872 C5895 C6015 C6042 C6049		See Note 1	See Note 2	D
Romiplostim	Powder for injection 375 micrograms	Injection	Nplate	AN	EMP	C3851 C3852 C3853 C3854		See Note 1	See Note 2	D
	Powder for injection 625 micrograms	Injection	Nplate	AN	EMP	C3851 C3852 C3853 C3854		See Note 1	See Note 2	D
Saquinavir	Tablet 500 mg (as mesylate)	Oral	Invirase	RO	EMP	C4454 C4512		240	5	D
Sevelamer	Tablet containing sevelamer hydrochloride 800 mg	Oral	Renagel	GZ	EMP	C5454 C5530		360	5	C
Sildenafil	Tablet 20 mg (as citrate)	Oral	APO-Sildenafil PHT	TX	EMP	C6065 C6066 C6085 C6086 C6089 C6114		See Note 1	See Note 2	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Revatio	PF	EMP	C6065 C6066 C6085 C6086 C6089 C6114		See Note 1	See Note 2	D
			Sildenafil AN PHT 20	EA	EMP	C6065 C6066 C6085 C6086 C6089 C6114		See Note 1	See Note 2	D
			SILDENAFIL-DRx	RZ	EMP	C6065 C6066 C6085 C6086 C6089 C6114		See Note 1	See Note 2	D
			Sildenafil Sandoz PHT 20	SZ	EMP	C4608 C4615 C4621 C4636 C4641		See Note 1	See Note 2	D
Simeprevir	Capsule 150 mg (as sodium)	Oral	Olysio	JC	EMP	C4669 C4684		42	0	D
Sirolimus	Tablet 0.5 mg	Oral	Rapamune	PF	EMP	C5794 C5795		200	5	C
	Tablet 1 mg	Oral	Rapamune	PF	EMP	C5794 C5795		200	5	C
	Tablet 2 mg	Oral	Rapamune	PF	EMP	C5794 C5795		200	5	C
	Oral solution 1 mg per mL, 60 mL	Oral	Rapamune	PF	EMP	C5794 C5795		200	5	C
Sofosbuvir	Tablet 400 mg	Oral	Sovaldi	GI	EMP	C5969 C5972	P5969	28	2	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					EMP	C5969 C5972	P5972	28	5	
Stavudine	Capsule 30 mg	Oral	Zerit	BQ	EMP	C4454 C4512		120	5	D
	Capsule 40 mg	Oral	Zerit	BQ	EMP	C4454 C4512		120	5	D
Sucroferric oxyhydroxide	Tablet, chewable, 2.5 g (equivalent to 500 mg iron)	Oral	Velphoro	FN	EMP	C5454 C5530		180	5	D
Tacrolimus	Capsule 0.5 mg	Oral	Pharmacor Tacrolimus 0.5	CR	EMP	C5569 C5602		200	5	D
			Prograf	LL	EMP	C5569 C5602		200	5	D
			TACROLIMUS APOTEX	TX	EMP	C5569 C5602		100	5	D
			Tacrolimus Sandoz	SZ	EMP	C5569 C5602		200	5	D
	Capsule 1 mg	Oral	Pharmacor Tacrolimus 1	CR	EMP	C5569 C5602		200	5	D
			Prograf	LL	EMP	C5569 C5602		200	5	D
			TACROLIMUS APOTEX	TX	EMP	C5569 C5602		100	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Tacrolimus Sandoz	SZ	EMP	C5569 C5602		200	5	D
	Capsule 5 mg	Oral	Pharmacor Tacrolimus 5	CR	EMP	C5569 C5602		100	5	D
			Prograf	LL	EMP	C5569 C5602		100	5	D
			TACROLIMUS APOTEX	TX	EMP	C5569 C5602		100	5	D
			Tacrolimus Sandoz	SZ	EMP	C5569 C5602		100	5	D
	Capsule 0.5 mg (once daily prolonged release)	Oral	Prograf XL	LL	EMP	C5569 C5602		60	5	D
	Capsule 1 mg (once daily prolonged release)	Oral	Prograf XL	LL	EMP	C5569 C5602		120	5	D
	Capsule 5 mg (once daily prolonged release)	Oral	Prograf XL	LL	EMP	C5569 C5602		60	5	D
Tadalafil	Tablet 20 mg	Oral	Adcirca	LY	EMP	C6065 C6066 C6071 C6089 C6112 C6127		See Note 1	See Note 2	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Telbivudine	Tablet 600 mg	Oral	Sebivo	NV	EMP	C4994 C4995		56	5	D
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg	Oral	Viread	GI	EMP	C4454 C4476 C4489 C4490 C4510 C4512		60	5	D
Tenofovir with Emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	Truvada	GI	EMP	C4454 C4512		60	5	D
Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	Oral	Atripla	GI	EMP	C4470 C4522		60	5	D
Tenofovir with emtricitabine, elvitegravir and cobicistat	Tablet containing elvitegravir 150 mg with cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg	Oral	Genvoya	GI	EMP	C4470 C4522		60	5	
	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	Oral	Stribild	GI	EMP	C4470 C4522		60	5	

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Tenofovir with Emtricitabine and Rilpivirine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and rilpivirine 25 mg (as hydrochloride)	Oral	Eviplera	GI	EMP	C4470 C4522		60	5	D
Tenofovir with emtricitabine, elvitegravir and cobicistat	Tablet containing elvitegravir 150 mg with cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg	Oral	Genvoya	GI	EMP	C4470 C4522		60	5	D
	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	Oral	Stribild	GI	EMP	C4470 C4522		60	5	D
Thalidomide	Capsule 50 mg	Oral	Thalomid	CJ	EMP	C5909 C5914		112	0	D
	Capsule 100 mg	Oral	Thalomid	CJ	EMP	C5909 C5914		56	0	D
Tipranavir	Capsule 250 mg	Oral	Aptivus	BY	EMP	C5764		240	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Actemra	RO	EMP	C4453 C4466 C4493 C4497 C4502 C4508 C4515 C4521 C4541 C4542 C4672 C4673 C5976 C5977 C5979 C6019 C6020 C6041 C6050 C6053		See Note 1	See Note 2	D
	Concentrate for injection 200 mg in 10 mL	Injection	Actemra	RO	EMP	C4453 C4466 C4493 C4497 C4502 C4508 C4515 C4521 C4541 C4542 C4672 C4673 C5976 C5977 C5979 C6019 C6020 C6041 C6050 C6053		See Note 1	See Note 2	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Concentrate for injection 400 mg in 20 mL	Injection	Actemra	RO	EMP	C4453 C4466 C4493 C4497 C4502 C4508 C4515 C4521 C4541 C4542 C4672 C4673 C5976 C5977 C5979 C6019 C6020 C6041 C6050 C6053		See Note 1	See Note 2	D
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	APO-Valaciclovir	TX	EMP	C5939 C5975		500	2	C
			Valaciclovir RBX	RA	EMP	C5939 C5975		500	2	C
			Valtrex	RW	EMP	C5939 C5975		500	2	C
			Zelitrex	RF	EMP	C5939 C5975		500	2	C
Valganciclovir	Tablet 450 mg (as hydrochloride)	Oral	Valcyte	RO	EMP	C4980 C4989 C5031		120	5	D
	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	Oral	Valcyte	RO	EMP	C4980 C4989 C5031		11	5	D

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Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Vedolizumab	Powder for injection 300 mg	Injection	Entyvio	TK	EMP	C5072 C5073 C5085 C5096 C5099 C5104 C5107 C5121 C5127 C5591		1	0	D
Zidovudine	Capsule 100 mg	Oral	Retrovir	VI	EMP	C4454 C4512		400	5	D
	Capsule 250 mg	Oral	Retrovir	VI	EMP	C4454 C4512		240	5	D
	Syrup 10 mg per mL, 200 mL	Oral	Retrovir	VI	EMP	C4454 C4512		15	5	D
Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	Injection	APO-Zoledronic Acid	TX	EMP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736		1	11	D
			DBL Zoledronic Acid	HH	EMP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736		1	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Zometa	NV	EMP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736		1	11	D
	Solution for I.V. infusion 4 mg (as monohydrate) in 100 mL	Injection	DBL Zoledronic Acid	HH	EMP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736		1	11	D
			Zometa	NV	EMP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736		1	11	D

Note 1: The quantity or number of units of the HSD pharmaceutical benefit that may be directed in a prescription to be supplied to an eligible patient on any 1 occasion may only be in accordance with the limitations set out in section 24.

Note 2: The maximum number of repeats that may be authorised in a repeated supply of the HSD pharmaceutical benefit is set out in section 25.

Schedule 2—Responsible Person Codes

Code	Responsible Person	Australian Business Number
AF	Alphapharm Pty Ltd	93 002 359 739
AN	Amgen Australia Pty Limited	31 051 057 428
AS	Aspen Pharmacare Australia Pty Ltd	51 096 236 985
AT	Actelion Pharmaceuticals Australia Pty Ltd	32 097 278 512
BD	Biogen Idec Australia Pty Ltd	30 095 760 115
BN	Bayer Australia Ltd	22 000 138 714
BQ	Bristol-Myers Squibb Australia Pty Ltd	33 004 333 322
BU	Bausch & Lomb (Australia) Pty Ltd	34 000 650 251
BY	Boehringer Ingelheim Pty Ltd	52 000 452 308
CJ	Celgene Pty Limited	42 118 998 771
CR	Pharmacor Pty Limited	58 121 020 835
DZ	Medsurge Healthcare Pty Ltd	92 124 728 892
EA	Amnel Pharma Australia Pty Ltd	21 447 854 484
FK	A.Menarini Australia Pty Ltd	62 116 935 758
FM	Fawns and McAllan Proprietary Limited	16 004 296 066
FM	Fawns and McAllan Proprietary Limited	16 004 296 066
FN	Fresenius Medical Care Australia Pty Ltd	80 067 557 877
GI	Gilead Sciences Pty Limited	71 072 611 708
GK	GlaxoSmithKline Australia Pty Ltd	47 100 162 481
GN	Actavis Pty Ltd	17 003 854 626
GO	BGP Products Pty Ltd	29 601 608 771
GQ	Generic Health Pty Ltd	93 110 617 859
GZ	Genzyme Australasia Pty Ltd	24 083 420 526
HH	Hospira Pty Limited	13 107 058 328
IS	Ipsen Pty Ltd	47 095 036 909
IX	Clinect Pty Ltd	76 150 558 473
JC	Janssen-Cilag Pty Ltd	47 000 129 975
LL	Astellas Pharma Australia Pty Ltd	81 147 915 482
LY	Eli Lilly Australia Pty Ltd	39 000 233 992
MK	Merck Sharp & Dohme (Australia) Pty Ltd	14 000 173 508
NV	Novartis Pharmaceuticals Australia Pty Limited	18 004 244 160
OA	Orphan Australia Pty Ltd	11 067 189 342
PF	Pfizer Australia Pty Ltd	50 008 422 348
QA	Aspen Pharma Pty Ltd	88 004 118 594
RA	Ranbaxy Australia Pty Ltd	17 110 871 826
RO	Roche Products Pty Ltd	70 000 132 865
RF	Arrow Pharma Pty Ltd	35 605 909 920
RW	Arrow Pharma Pty Ltd	35 605 909 920
RZ	Dr Reddy's Laboratories Australia Pty Ltd	16 120 092 408
SZ	Sandoz Pty Ltd	60 075 449 553
TB	Teva Pharma Australia Pty Limited	41 169 715 664
TD	Stada Pharmaceuticals Australia Pty Limited	73 154 966 944
TK	Takeda Pharmaceuticals Australia Pty Ltd	71 095 610 870

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Code	Responsible Person	Australian Business Number
TX	Apotex Pty Ltd	52 096 916 148
VE	AbbVie Pty Ltd	48 156 384 262
VI	ViiV Healthcare Pty Ltd	46 138 687 448
VR	Vertex Pharmaceuticals (Australia) Pty Ltd	34 160 157 157
XA	Pharmaxis Ltd	75 082 811 630
XI	Alexion Pharmaceuticals Australasia Pty Ltd	59 132 343 036
YA	Agila Australasia Pty Ltd	12 154 055 339
ZF	Sun Pharmaceutical Industries (Australia) Pty Ltd	64 130 119 603
ZI	Shire Australia Pty Limited	29 128 941 819

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Schedule 3—Circumstances and Purposes Codes

(sections 9, 14, 15, 16 and 25)

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Abacavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Abacavir with Lamivudine	C4527		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4527
	C4528		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4528
Abacavir with Lamivudine and Zidovudine	C4480		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4480

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4495		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4495
Abatacept	C4695	P4695	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply. Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with modified Authority Required procedures
	C4734	P4734	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Continuing Treatment – balance of supply. Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with modified Authority Required procedures
	C5456	P5456	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have a documented history of severe active rheumatoid arthritis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND Patient must not receive more than 16 weeks of treatment under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C5493	P5493	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) Patient must have severe active rheumatoid arthritis, AND Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND Patient must not receive more than 16 weeks of treatment under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(3) a signed patient acknowledgement. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised. Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial,	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.	
	C5523	P5523	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Continuing treatment Patient must have a documented history of severe active rheumatoid arthritis, AND Patient must have demonstrated an adequate response to treatment with this drug, AND Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
Adalimumab	C4464		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — initial treatment (new patient or patient recommencing treatment after a break of more than 12 months) Patient must have severe active juvenile idiopathic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and (3) an acknowledgement signed by a parent or authorised guardian. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.	
	C4465		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — continuing treatment Patient must have a documented history of severe active juvenile idiopathic arthritis; AND Patient must have demonstrated an adequate response to treatment with adalimumab; AND Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.	
	C4491		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — initial treatment 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4500		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — continuing treatment – balance of supply Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures
	C4546		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — initial treatment 2 (change or recommencement of treatment after break of less than 12 months) Patient must have a documented history of severe active juvenile idiopathic arthritis; AND Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
Adefovir	C4490		Chronic hepatitis B Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4490
	C4510		Chronic hepatitis B Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L,	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4510

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			bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	
Alemtuzumab	C4829	P4829	Where the patient is receiving treatment at/from a public hospital Multiple sclerosis – Continuing treatment Patient must have previously been issued with an authority prescription for this drug, Patient must not show continuing progression of disability while on treatment with this drug, and Patient must not receive more than one PBS-subsidised treatment per year. Treatment must be as monotherapy, and Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4829
	C4834	P4834	Where the patient is receiving treatment at/from a public hospital Multiple sclerosis – Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, The treatment must be as monotherapy, Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4834
	C4838	P4838	Where the patient is receiving treatment at/from a private hospital Multiple sclerosis - Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, The treatment must be as monotherapy,	Compliance with Written and Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.	
	C4850	P4850	Where the patient is receiving treatment at/from a private hospital Multiple sclerosis – Continuing treatment Patient must have previously been issued with an authority prescription for this drug, Patient must not show continuing progression of disability while on treatment with this drug, Patient must not receive more than one PBS-subsidised treatment per year, The treatment must be as monotherapy, Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Written and Telephone Authority Required procedures
Ambrisentan	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	

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			PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	Compliance with modified Authority Required procedures
	C6078	P6078	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients) Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to	

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			re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
	C6089	P6089	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	Compliance with modified Authority Required procedures
	C6102	P6102	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.	

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			Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an	

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			assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6117	P6117	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
Anakinra	C5450	P5450	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe cryopyrin associated periodic syndromes (CAPS) Must be treated by a rheumatologist or in consultation with a rheumatologist; OR Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5450
Apomorphine	C4833	P4833	Where the patient is receiving treatment at/from a public hospital Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4833
	C4860	P4860	Where the patient is receiving treatment at/from a private hospital Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.	Compliance with Written and Telephone Authority Required procedures
Atazanavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Atazanavir with cobicistat	C4454	P4454	HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4512	P4512	HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Azacitidine	C6132	P6132	Where the patient is receiving treatment at/from a private or public hospital Chronic Myelomonocytic Leukaemia Initial treatment The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and (d) a copy of the full blood examination report; and (e) a signed patient acknowledgement. No more than 3 cycles will be authorised.	Compliance with modified Authority Required procedures
	C6143	P6143	Where the patient is receiving treatment at/from a private or public hospital Acute Myeloid Leukaemia Initial treatment The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and (d) a copy of the full blood examination report; and (e) a signed patient acknowledgement. No more than 3 cycles will be authorised.	Compliance with modified Authority Required procedures
	C6144	P6144	Where the patient is receiving treatment at/from a private or public hospital Chronic Myelomonocytic Leukaemia Continuing treatment	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	
	C6177	P6177	Where the patient is receiving treatment at/from a private or public hospital Myelodysplastic syndrome Initial treatment The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations: a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias. Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations: a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (d) a copy of the full blood examination report; and (e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and (f) a signed patient acknowledgment form. No more than 3 cycles will be authorised.	
	C6186	P6186	Where the patient is receiving treatment at/from a private or public hospital Acute Myeloid Leukaemia Continuing treatment The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with modified Authority Required procedures
	C6199	P6199	Where the patient is receiving treatment at/from a private or public hospital Myelodysplastic syndrome Continuing treatment The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with modified Authority Required procedures
Azithromycin	C1299		Where the patient is receiving treatment at/from a private hospital Prophylaxis against Mycobacterium avium complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3317		Where the patient is receiving treatment at/from a public hospital Prophylaxis against Mycobacterium avium complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3317
Baclofen	C5985	P5985	Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Written or Telephone Authority Required procedures
	C5990	P5990	Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5990
	C6000	P6000	Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 6000
	C6003	P6003	Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 6003
	C6025	P6025	Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Written or Telephone Authority Required procedures
	C6051	P6051	Where the patient is receiving treatment at/from a public hospital	Compliance with Written or

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Telephone Authority Required procedures - Streamlined Authority Code 6051
	C6052	P6052	Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Written or Telephone Authority Required procedures
	C6054	P6054	Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Written or Telephone Authority Required procedures
Boceprevir	C4182		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection Must be treated in an accredited treatment centre; Patient must have compensated liver disease; Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; The treatment must be in combination with peginterferon alfa and ribavirin; The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis; The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12; The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24; Patient must be 18 years or older; Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4182

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			their partners must each be using an effective form of contraception if of child-bearing age Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed	
	C4196		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection Must be treated in an accredited treatment centre; Patient must have compensated liver disease; Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; The treatment must be in combination with peginterferon alfa and ribavirin; The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis; The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24; Patient must be 18 years or older; Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed	
	C4202		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection Must be treated in an accredited treatment centre; Patient must have compensated liver disease; Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; The treatment must be in combination with peginterferon alfa and ribavirin; The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis; The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24; Patient must be 18 years or older; Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4202
	C4205		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection Must be treated in an accredited treatment centre; Patient must have compensated liver disease; Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; The treatment must be in combination with peginterferon alfa and ribavirin; The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			responders to the prior course of interferon based therapy for hepatitis C; OR The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis; The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12; The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24; Patient must be 18 years or older; *Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed. For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed	
Bosentan	C4628	P4628	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Cessation of treatment (all patients) Patient must have received approval for initial PBS-subsidised treatment with this agent; AND Patient must have not responded to prior PBS-subsidised therapy with this agent; AND The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.	Compliance with modified Authority Required procedures
	C6063	P6063	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH)	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) two completed authority prescription forms; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows:	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.	

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			The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6064	P6064	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients) Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) two completed authority prescription forms; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	
	C6089	P6089	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	Compliance with modified Authority Required procedures
	C6107	P6107	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology); AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) two completed authority prescription forms; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
Clarithromycin	C5873	P5873	Where the patient is receiving treatment at/from a private hospital Mycobacterium avium complex infection	Compliance with Written or Telephone Authority Required procedures
	C5874	P5874	Where the patient is receiving treatment at/from a private hospital Mycobacterium avium complex infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5874
Clozapine	C4998		Schizophrenia Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition, AND Patient must have completed at least 18 weeks therapy, AND Patient must be on a clozapine dosage considered stable by a treating psychiatrist, AND The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. Must be treated by a psychiatrist; OR Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4998
	C5001		Where the patient is receiving treatment at/from a private hospital Schizophrenia Initial treatment Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5015		Where the patient is receiving treatment at/from a public hospital Schizophrenia Initial treatment Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5015
Cyclosporin	C1504		Where the patient is receiving treatment at/from a private hospital For use by organ or tissue transplant recipients	Compliance with Written or Telephone Authority Required procedures
	C1654		Where the patient is receiving treatment at/from a private hospital Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C1655		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures
	C1656		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life	Compliance with Written or Telephone Authority Required procedures
	C1657		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C1658		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures
	C3328		Where the patient is receiving treatment at/from a public hospital Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3328
	C3329		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3329
	C3330		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3330
	C3331		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3331
	C3332		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3332
	C3333		Where the patient is receiving treatment at/from a public hospital For use by organ or tissue transplant recipients	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3333
Daclatasvir	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND	Compliance with Written or Telephone Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	procedures
	C5972	P5972	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks.	Compliance with Written or Telephone Authority Required procedures
Darbepoetin Alfa	C6260		Where the patient is receiving treatment at/from a private hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures
	C6294		Where the patient is receiving treatment at/from a public hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
Darunavir	C4313	P4313	Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND The treatment must be co-administered with 100 mg ritonavir, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, AND Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4313

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5094	P5094	Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND The treatment must be co-administered with 100 mg ritonavir twice daily, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5094
Deferasirox	C3828		Where the patient is receiving treatment at/from a public hospital Chronic iron overload in patients with disorders of erythropoiesis	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 3828
	C3829		Where the patient is receiving treatment at/from a private hospital Chronic iron overload in patients with disorders of erythropoiesis.	Compliance with Written or Telephone Authority Required procedures
Deferiprone	C1911		Where the patient is receiving treatment at/from a private hospital Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;	Compliance with Written or Telephone Authority Required procedures
	C1912		Where the patient is receiving treatment at/from a private hospital Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.	Compliance with Written or Telephone Authority Required procedures
	C3338		Where the patient is receiving treatment at/from a public hospital Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3338
	C3339		Where the patient is receiving treatment at/from a public hospital Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3339
Desferrioxamine	C1085		Where the patient is receiving treatment at/from a private hospital	Compliance with Written or

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Disorders of erythropoiesis associated with treatment-related chronic iron overload.	Telephone Authority Required procedures
	C3340		Where the patient is receiving treatment at/from a public hospital Disorders of erythropoiesis associated with treatment-related chronic iron overload	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3340
Didanosine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Dolutegravir	C4454		HIV infection Continuing treatment Patient must have previously received PBS subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Dolutegravir with abacavir and lamivudine	C4480	P4480	HIV infection – Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection. Patient must be aged 12 years or older, and must weigh 40 kg or more.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4480
	C4495	P4495	HIV infection – Initial treatment Patient must be antiretroviral treatment naive. Patient must be aged 12 years or older, and Patient must weigh 40 kg or more.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4495

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Dornase alfa	C5634		Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. Patient must be less than 5 years of age. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5634
	C5635		Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Treatment Phase: Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years,AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5635
	C5715		Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Treatment Phase: Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	
	C5740		Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5740
	C5768		Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	
	C5800		Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. Patient must be less than 5 years of age. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.	Compliance with Written or Telephone Authority Required procedures
Doxorubicin - Pegylated Liposomal	C6233		Where the patient is receiving treatment at/from a private hospital Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures
	C6234		Where the patient is receiving treatment at/from a public hospital Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6234
	C6264		Where the patient is receiving treatment at/from a private hospital	Compliance with Authority

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			Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Required procedures
	C6274		Where the patient is receiving treatment at/from a public hospital Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6274
Eculizumab	C5926	P5926	Atypical haemolytic uraemic syndrome (aHUS) - Continuing treatment Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, AND Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and (3) A copy of a current Certificate of vaccination; and (4) A measurement of body weight at the time of application; and (5) An identified genetic mutation, if applicable; and (6) A family history of aHUS, if applicable; and (7) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and (8) A history of kidney transplant if applicable (especially if required due to aHUS); and (9) An inclusion of the individual consequences of recurrent disease, if applicable; and (10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
	C5929	P5929	Atypical haemolytic uraemic syndrome (aHUS) - Extended Continuing treatment Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, AND Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition,	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			AND Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR Patient must have severe TMA-related neurological impairment; OR Patient must have severe TMA-related gastrointestinal impairment; OR Patient must have severe TMA-related pulmonary impairment; OR Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is: (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include: (1) A completed authority prescription form; and	

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			(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and (3) A copy of a current Certificate of vaccination; and (4) A measurement of body weight at the time of application; and (5) An identified genetic mutation, if applicable; and (6) A family history of aHUS, if applicable; and (7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and (8) A history of kidney transplant, if applicable (especially if required due to aHUS); and (9) An inclusion of the individual consequences of recurrent disease; and (10) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
	C5930	P5930	Atypical haemolytic uraemic syndrome (aHUS) - Recommencement of treatment Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, AND Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L);OR(iii) TMA-related organ impairment including on recent biopsy, AND *Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist,	Compliance with modified Authority Required procedures

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			or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is: (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include: (1) A completed authority prescription form(s); and (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) A copy of a current Certificate of vaccination; and (5) A measurement of body weight at the time of application, and (6) An identified genetic mutation, if applicable; and (7) A family history of aHUS if applicable; and (8) A history of multiple episodes of aHUS following the treatment break, if applicable; and (9) A history of kidney transplant if applicable (especially if required due to aHUS); and (10) An inclusion of the individual consequences of recurrent disease; and	

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			(11) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy; (12) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
	C5931	P5931	Atypical haemolytic uraemic syndrome (aHUS) - Initial treatment – Balance of Supply Patient must have received PBS-subsidised initial supply of eculizumab for this condition, AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, AND Patient must not receive more than 20 weeks supply under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.	Compliance with modified Authority Required procedures
	C5932	P5932	Atypical haemolytic uraemic syndrome (aHUS) - Grandfather eculizumab patient Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), AND Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, AND	Compliance with modified Authority Required procedures

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			Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, AND Patient must have received treatment with eculizumab within the last 6 months at the time of application, AND Patient must have demonstrated on-going treatment response as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, AND Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, AND Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. Evidence of active and progressing TMA is defined by the following: (1) a platelet count of less than 150x10^9/L; and evidence of two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; OR (2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment	

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			A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is: (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) A copy of a current Certificate of vaccination; and (5) A measurement of body weight at the time of application; and (6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and (7) An identified genetic mutation, if applicable; and (8) A family history of aHUS, if applicable; and (9) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and (10) A history of kidney transplant if applicable (especially if required due to aHUS); and (11) An inclusion of the individual consequences of recurrent disease; and (12) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6	

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			months at the time of application; and (13) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and (14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and (15) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and (16) Where available in the week prior to commencing eculizumab results demonstrating: (a) a platelet count of less than 150 x10^9/L; and evidence of two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; OR (b) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND (c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment; and (17) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.	

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			This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
	C5933	P5933	Atypical haemolytic uraemic syndrome (aHUS) - Initial treatment Patient must have active and progressing thrombotic microangiopathy (TMA),AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, AND Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, AND Patient must have clinical features of active organ damage or impairment, AND Patient must not receive more than 4 weeks of treatment under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. Evidence of active and progressing TMA is defined by the following: (1) a platelet count of less than 150x10^9/L; and evidence of two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; OR (2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment;	Compliance with modified Authority Required procedures

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			(d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) A copy of a current Certificate of vaccination; and (5) A measurement of body weight at the time of application; and (6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and (7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - balance of supply; and (8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and (9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and (10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.	
	C5934	P5934	Atypical haemolytic uraemic syndrome (aHUS) - Continuing recommencement of treatment Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, AND Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, AND Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this	Compliance with modified Authority Required procedures

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			condition, AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is: (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and (3) A copy of a current Certificate of vaccination; and (4) A measurement of body weight at the time of application; and (5) An identified genetic mutation, if applicable; and (6) A family history of aHUS, if applicable; and (7) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and (8) A history of kidney transplant if applicable (especially if required due to aHUS); and (9) An inclusion of the individual consequences of recurrent disease, if applicable; and	

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			(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
	C5935	P5935	Atypical haemolytic uraemic syndrome (aHUS) - Extended initial treatment - Assessment phase Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, AND Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND Patient must not receive more than 56 weeks of treatment under this restriction. Patient must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A treatment failure is defined as a patient who is: (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab. The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment). The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and (3) A copy of a current Certificate of vaccination; and (4) A measurement of body weight at the time of application; and (5) An identified genetic mutation, if applicable; and (6) A family history of aHUS, if applicable; and (7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and (8) A history of kidney transplant, if applicable, (especially if required due to aHUS); and (9) An inclusion of the individual consequences of recurrent disease, if applicable; and (10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required. This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.	
Efavirenz	C4454		HIV infection	Compliance with Written or

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Eltrombopag	C3855		Where the patient is receiving treatment at/from a private or public hospital Initial (new patients) Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is: (1) Splenectomised and: (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy; or (2) Not splenectomised and: (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and (c) in whom splenectomy is contraindicated for medical reasons. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application: (a) a platelet count of less than or equal to 20,000 million per L; or (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a signed patient acknowledgement, (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. The full blood count must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion	
	C3856		Where the patient is receiving treatment at/from a private or public hospital Initial (previous treatment with eltrombopag not PBS-subsidised) Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a signed patient acknowledgement, (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, and (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion	Compliance with modified Authority Required procedures
	C3857		Where the patient is receiving treatment at/from a private or public hospital Continuing therapy or re-initiation after a break in therapy First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For the purposes of this restriction, a sustained platelet response is defined as use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag, and either of the following: (a) a platelet count greater than or equal to 50,000 million per L on at least four occasions, each at least one week apart; or (b) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four occasions, each at least one week apart. Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: (1) a completed authority prescription form, (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The most recent platelet count must be no more than one month old at the time of application. A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone	
	C3858		Where the patient is receiving treatment at/from a private or public hospital Second and subsequent applications for continuing therapy Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag. For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag, and either of the following:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(a) a platelet count greater than or equal to 50,000 million per L; or (b) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone	
Emtricitabine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Enfuvirtide	C5014		HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5014
Entecavir	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4993

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5036
	C5037		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have failed lamivudine, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5037
	C5044		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have failed lamivudine, AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5044
Epoetin Alfa	C6260		Where the patient is receiving treatment at/from a private hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures
	C6294		Where the patient is receiving treatment at/from a public hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Epoetin Beta	C6260		Where the patient is receiving treatment at/from a private hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures
	C6294		Where the patient is receiving treatment at/from a public hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
Epoetin Lambda	C6245		Where the patient is receiving treatment at/from a public hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6245
	C6261		Where the patient is receiving treatment at/from a private hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Epoprostenol	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	
	C6090	P6090	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (change or re-commencement of therapy for all patients) Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			drug they are ceasing.	
	C6122	P6122	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6123	P6123	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	
Etanercept	C4459		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — continuing treatment – balance of supply Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures
	C4461		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis—initial treatment 1 (new patient or patient recommencing treatment after a break of more than 12 months) Patient must have severe active juvenile idiopathic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and (3) an acknowledgement signed by a parent or authorised guardian. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.	
	C4486		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — initial treatment 2 (change or recommencement of treatment after break of less than 12 months) Patient must have a documented history of severe active juvenile idiopathic arthritis; Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			to have failed to respond to treatment with etanercept. If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C4487		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — initial treatment 1 (new patient or patient recommencing treatment after a break of more than 12 months) or initial treatment 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures
	C4540		Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis — continuing treatment Patient must have a documented history of severe active juvenile idiopathic arthritis; AND Patient must have demonstrated an adequate response to treatment with etanercept; AND Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			anti-rheumatic drug (bDMARD) treatment in this treatment cycle; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Etravirine	C5014		HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5014
Everolimus	C5554	P5554	Where the patient is receiving treatment at/from a public hospital Management of cardiac allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5554
	C5555	P5555	Where the patient is receiving treatment at/from a private hospital Management of cardiac allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5794	P5794	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5795	P5795	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5795

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Filgrastim	C2912		Where the patient is receiving treatment at/from a private hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;	Compliance with Written or Telephone Authority Required procedures
	C2913		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;	Compliance with Written or Telephone Authority Required procedures
	C2914		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;	Compliance with Written or Telephone Authority Required procedures
	C2915		Where the patient is receiving treatment at/from a private hospital A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;	Compliance with Written or Telephone Authority Required procedures
	C2916		Where the patient is receiving treatment at/from a private hospital A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;	Compliance with Written or Telephone Authority Required procedures
	C2917		Where the patient is receiving treatment at/from a private hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2918		Where the patient is receiving treatment at/from a private hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2919		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			planned;	
	C2920		Where the patient is receiving treatment at/from a private hospital A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);	Compliance with Written or Telephone Authority Required procedures
	C2921		Where the patient is receiving treatment at/from a private hospital A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));	Compliance with Written or Telephone Authority Required procedures
	C2922		Where the patient is receiving treatment at/from a private hospital A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));	Compliance with Written or Telephone Authority Required procedures
	C2923		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures
	C2924		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures
	C2925		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures
	C2926		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C2927		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures
	C2928		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures
	C2929		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures
	C2930		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures
	C3087		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C3187		Where the patient is receiving treatment at/from a private hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.	Compliance with Written or Telephone Authority Required procedures
	C3357		Where the patient is receiving treatment at/from a public hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3357

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3358		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3358
	C3359		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3359
	C3360		Where the patient is receiving treatment at/from a public hospital A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3360
	C3361		Where the patient is receiving treatment at/from a public hospital A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3361
	C3362		Where the patient is receiving treatment at/from a public hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3362
	C3363		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3363

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3364		Where the patient is receiving treatment at/from a public hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3364
	C3365		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3365
	C3366		Where the patient is receiving treatment at/from a public hospital A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3366
	C3367		Where the patient is receiving treatment at/from a public hospital A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3367
	C3368		Where the patient is receiving treatment at/from a public hospital A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3368
	C3369		Where the patient is receiving treatment at/from a public hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3369

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	
	C3370		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3370
	C3371		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3371
	C3372		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3372
	C3373		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3373
	C3374		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3374
	C3375		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3375
	C3376		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3376

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3377		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3377
	C3833		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)	Compliance with Written or Telephone Authority Required procedures
	C3834		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 3834
Fosamprenavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Foscarnet	C4973		Herpes simplex virus infection The condition must be aciclovir resistant, AND Patient must have HIV infection.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4973
	C4980		Cytomegalovirus retinitis Clinical criteria: Patient must have HIV infection.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4980

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Ganciclovir	C4972		Where the patient is receiving treatment at/from a public hospital Cytomegalovirus disease Prophylaxis Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4972
	C4990		Where the patient is receiving treatment at/from a private hospital Cytomegalovirus disease Prophylaxis Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Written and Telephone Authority Required procedures
	C4999		Where the patient is receiving treatment at/from a public hospital Cytomegalovirus disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4999
	C5000		Cytomegalovirus retinitis Patient must be severely immunocompromised, including due to HIV infection.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5000
	C5025		Where the patient is receiving treatment at/from a private hospital Cytomegalovirus disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Written and Telephone Authority Required procedures
Ibandronic acid	C5257	P5257	Where the patient is receiving treatment at/from a private hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written and Telephone Authority Required procedures
	C5291	P5291	Where the patient is receiving treatment at/from a public hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5291
Iloprost	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	
	C6077	P6077	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR Patient must have WHO Functional Class IV drug-induced PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C6089	P6089	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	Compliance with modified Authority Required procedures
	C6113	P6113	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients) Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
	C6128	P6128	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with this agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III drug-induced PAH; AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
Indinavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Infliximab	C3691	P3691	Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment 1 Initial treatment commencing a treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) has an externally draining enterocutaneous or rectovaginal fistula; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the most recent fistula assessment is no more than 1 month old at the time of application; a course of initial treatment commencing a treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone	
	C3693	P3693	Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment 3 (previous infliximab treatment non-PBS-subsidised) Commencement of a treatment cycle with an initial PBS-subsidised course of infliximab for continuing treatment, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who satisfies the following criteria: (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment,	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			as outlined in the restriction for continuing treatment; and (d) is receiving treatment with infliximab at the time of application; and (e) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the application for authorisation is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the current fistula assessment is no more than 1 month old at the time of application; the baseline fistula assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; a patient is eligible for PBS-subsidised treatment under this restriction once only	
	C3819	P3819	Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment 2 (change or recommencement of PBS-subsidised treatment) Initial treatment, or recommencement of treatment, with infliximab within an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			disease who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where TNF-alfa antagonist means adalimumab or infliximab; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment; the most recent fistula assessment is no more than 1 month old at the time of application; to demonstrate a response to treatment the application must be accompanied by the results of the patient's most recent course of TNF-alfa antagonist therapy; the assessment of response to the most recent course of TNF-alfa antagonist therapy must: (a) be provided to the Chief Executive Medicare no later than 4 weeks from the date that course was ceased; and (b) have been made following a minimum of 12 weeks of treatment if the course of therapy was a 16-week initial course of adalimumab, and up to 12 weeks after the first dose (6 weeks following the third dose) if the course of therapy was a 3 dose initial course of infliximab; if the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			telephone	
	C3820	P3820	Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — continuing treatment Continuing PBS-subsidised treatment with infliximab within an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition; the fistula assessment is no more than 1 month old at the time of application; the assessment of the patient's response to a course of treatment is provided to the Chief Executive Medicare no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (up to 6 weeks following the third dose); where an assessment is not submitted to the Chief Executive Medicare within the timeframes specified above, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response	
	C4524	P4524	Where the patient is receiving treatment at/from a public hospital Acute severe ulcerative colitis Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital Patient must be 6 years of age or older Must be treated by a gastroenterologist; OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology] For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where: (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4524

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records	
	C4535	P4535	Where the patient is receiving treatment at/from a private hospital Acute severe ulcerative colitis Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital Patient must be 6 years of age or older Must be treated by a gastroenterologist; OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology] For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where: (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4603	P4603	Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis Treatment Phase: Initial 2 (change or recommencement for all patients) Clinical criteria: Patient must have a documented history of active ankylosing spondylitis; AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle; AND Patient must be eligible to receive further bDMARD therapy. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. A maximum of 18 weeks of treatment with this drug will be approved under this criterion. At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.	
	C4625	P4625	Where the patient is receiving treatment at/from a private or public hospital Active ankylosing spondylitis Treatment Phase: Initial 1 (new patients) Clinical criteria: The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) a signed patient acknowledgment. The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. A maximum of 18 weeks of treatment with this drug will be approved under this criterion. At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.	
	C4626	P4626	Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply Clinical criteria: Patient must have active, or a documented history of active, ankylosing spondylitis; AND	Compliance with modified Authority Required procedures

Corrected Authorised Version registered 31/10/2016 F2016C00679

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment; AND The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist.	
	C4627	P4627	Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis Treatment Phase: Continuing treatment – balance of supply Clinical criteria: Patient must have a documented history of active ankylosing spondylitis; AND Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist.	Compliance with modified Authority Required procedures
	C4630	P4630	Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis Treatment Phase: Continuing treatment Clinical criteria: Patient must have a documented history of active ankylosing spondylitis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.	
	C4705	P4705	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply. Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment; AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	
	C4718	P4718	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Continuing Treatment – balance of supply. Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with modified Authority Required procedures
	C4846	P4846	Where the patient is receiving treatment at/from a private or public hospital Severe psoriatic arthritis - Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; or must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	Compliance with modified Authority Required procedures
	C4854	P4854	Where the patient is receiving treatment at/from a private or public hospital Severe psoriatic arthritis - Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; or Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Treatment criteria:must be treated by a rheumatologist; or must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	
	C5077	P5077	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe Crohn disease Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI Patient must have a documented history of moderate to severe Crohn disease, AND Patient must have previously been issued with an authority prescription for this drug for this condition, AND Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or a specialist paediatric gastroenterologist. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition. The PCDAI assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response. A maximum of 24 weeks treatment will be authorised under this criterion. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.	
	C5078	P5078	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Change or Re-commencement of treatment (initial 2) Patient must have a documented history of severe Crohn disease, AND Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(iii) the date of clinical assessment; and (iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	
	C5079	P5079	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients) Patient must be 6 years of age or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services. Written applications for authority approval for sufficient therapy to complete balance of supply should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001	
	C5084	P5084	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment). Patient must be aged 18 years or older.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.	
	C5097	P5097	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe Crohn disease Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1) Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or a specialist paediatric gastroenterologist.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription forms; and (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and (iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au). A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.	
	C5103	P5103	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe Crohn disease Balance of supply for a paediatric patient Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, AND The treatment must provide no more than the balance of up to 3 doses or 2 repeats. Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or a specialist paediatric gastroenterologist.	Compliance with modified Authority Required procedures
	C5109	P5109	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe Crohn disease Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2) Patient must have a documented history of moderate to severe Crohn disease, AND Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Patient must be aged 6 to 17 years inclusive. Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or a specialist paediatric gastroenterologist. To demonstrate a response to treatment the application must be accompanied by the results of the most recent	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			criterion for PBS-subsidised treatment with this drug.	
	C5110	P5110	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Continuing treatment Patient must have a documented history of severe Crohn disease, AND Patient must have previously been issued with an authority prescription for this drug for this condition, AND Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. Up to a maximum of 2 repeats will be authorised.	
	C5111	P5111	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Continuing treatment Patient must have previously been issued with an authority prescription for this drug for this condition, AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.	
	C5112	P5112	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Initial PBS-subsidised treatment (Grandfather patient) Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 December 2014, AND Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Patient must be 6 years of age or older. Must be treated by a gastroenterologist (code 87); OR	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) the date of commencement of this drug; and (iii) the signed patient acknowledgement. The current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. 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.	
	C5118	P5118	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Initial treatment (new patient - initial 1) Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			contraindication to steroids, AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment; and (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			otherwise extend the relevant treatment phase. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	
	C5120	P5120	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Initial treatment (new patient - Initial 1) Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years). Patient must be 6 years of age or older.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the signed patient acknowledgement. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application. Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website.	
	C5149	P5149	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 22 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	Compliance with modified Authority Required procedures
	C5197	P5197	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			time of initial diagnosis; AND Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and (iii) the signed patient and prescriber acknowledgements. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.	
	C5233	P5233	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and (iii) the signed patient and prescriber acknowledgements. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based	

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			on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.	
	C5234	P5234	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.	
	C5303	P5303	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Initial treatment – Initial 2, Whole body (change or recommencement of treatment) Patient must have a documented history of severe chronic plaque psoriasis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(ii) details of prior biological treatment, including dosage, date and duration of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised. Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.	
	C5304	P5304	Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have a documented history of severe chronic plaque psoriasis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			respond to treatment with this drug. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.	
	C5376	P5376	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment) Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised. Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.	
	C5377	P5377	Where the patient is receiving treatment at/from a private or public hospital Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Must be treated by a dermatologist.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5440	P5440	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Continuing treatment Patient must have a documented history of severe active rheumatoid arthritis, AND Patient must have demonstrated an adequate response to treatment with infliximab, AND Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised. All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C5484	P5484	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) Patient must have severe active rheumatoid arthritis, AND Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND Patient must not receive more than 22 weeks of treatment under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.	
	C5485	C5485	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months). Patient must have a documented history of severe active rheumatoid arthritis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND Patient must not receive more than 22 weeks of treatment under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C5570	P5570	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2) Patient must have previously been issued with an authority prescription for infliximab or vedolizumab for this condition	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle. Patient must be treated by a gastroenterologist (code 87); OR Patient must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Patient must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Patient must be treated by a paediatrician; OR Patient must be treated by a specialist paediatric gastroenterologist. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.	
	C6076	P6076	Where the patient is receiving treatment at/from a private or public hospital Severe psoriatic arthritis Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) Patient must have severe active psoriatic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be an adult. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C6082	P6082	Where the patient is receiving treatment at/from a private or public hospital Severe psoriatic arthritis Initial treatment – Initial 2 (change or recommencement of treatment) Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be an adult. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised. Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug. Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			weeks from the date that course was ceased. Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C6110	P6110	Where the patient is receiving treatment at/from a private or public hospital Severe psoriatic arthritis Continuing treatment Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be an adult. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:	Compliance with modified Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.	
Interferon alfa-2a	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4993
	C5003		Where the patient is receiving treatment at/from a private hospital Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy	Compliance with Written and Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			should be monitored. Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5036
	C5042		Where the patient is receiving treatment at/from a public hospital Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5042
Interferon alfa-2b	C4974		Where the patient is receiving treatment at/from a public hospital Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Malignant melanoma The treatment must be as adjunctive therapy to current standard care, AND Patient must have undergone surgery, AND The condition must include nodal involvement.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4974
	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4993

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5003		Where the patient is receiving treatment at/from a private hospital Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Written and Telephone Authority Required procedures
	C5033		Where the patient is receiving treatment at/from a private hospital Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Malignant melanoma The treatment must be as adjunctive therapy to current standard care, AND Patient must have undergone surgery, AND The condition must include nodal involvement.	Compliance with Written and Telephone Authority Required procedures
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5036
	C5042		Where the patient is receiving treatment at/from a public hospital Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5042

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Interferon Gamma-1b	C6222		Where the patient is receiving treatment at/from a public hospital Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6222
	C6286		Where the patient is receiving treatment at/from a private hospital Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Authority Required procedures
Ivacaftor	C5492	P5492	Where the patient is receiving treatment at/from a private or public hospital Cystic fibrosis Treatment Phase: Continuing treatment Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, AND Patient must not receive more than 24 weeks of treatment under this restriction, AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 6 years of age or older. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will	Compliance with Written Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			last for 28 weeks. Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and (3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and (5) a recent sweat chloride result; and (6) height and weight measurements at the time of application; and (7) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.	
	C5507	P5507	Where the patient is receiving treatment at/from a private or public hospital Cystic fibrosis Treatment Phase: Initial treatment - Grandfather patients Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014, AND Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND Patient must not receive more than 24 weeks of treatment under this restriction, AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 6 years of age or older. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include:	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) a completed authority prescription form; and (2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and (5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and (6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and (7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and (8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and (9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and (10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and (11) height and weight measurements at the time of application; and (12) height and weight measurements performed immediately prior to commencement of ivacaftor; and (13) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and (14) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and (15) dates of prior ivacaftor therapy.	
	C5531	P5531	Where the patient is receiving treatment at/from a private or public hospital Cystic fibrosis Treatment Phase: Initial treatment – New patients Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not receive more than 24 weeks of treatment under this restriction, AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 6 years of age or older. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III)	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			mutation on the CFTR gene; and (5) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and (6) evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and (7) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and (8) a copy of a sweat chloride result; and (9) height and weight measurements at the time of application; and (10) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.	
Lamivudine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4993
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5036

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			initiating therapy.	
Lamivudine with zidovudine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Lanreotide	C4559		Where the patient is receiving treatment at/from a private hospital Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures
	C4567		Where the patient is receiving treatment at/from a public hospital Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4567

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	
	C4569		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures
	C4570		Where the patient is receiving treatment at/from a public hospital Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4570

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4574		Where the patient is receiving treatment at/from a private hospital Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures
	C4575		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4575
Lanthanum	C5454	P5454	Where a patient is receiving treatment at/from a private hospital Hyperphosphataemia Treatment Phase: Initiation and stabilisation The condition must not be adequately controlled by calcium,AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must not be used in combination with any other non-calcium phosphate binding agents. reatment criteria: Patient must be undergoing dialysis for chronic kidney disease.	
	C5530	P5530	Where a patient is receiving treatment at/from a public hospital Hyperphosphataemia Treatment Phase: Initiation and stabilisation The condition must not be adequately controlled by calcium, AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Treatment criteria: Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5530
Ledipasvir with sofosbuvir	C5944	P5944	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 8 weeks.	Compliance with Written or Telephone Authority Required procedures
	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Written or Telephone Authority Required procedures
	C5972	P5972	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Lenalidomide	C4090		Where the patient is receiving treatment at/from a private or public hospital Multiple myeloma Initial PBS-subsidised treatment The condition must be confirmed by a histological diagnosis, The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone, Patient must have progressive disease after at least one prior therapy, Patient must have undergone or be ineligible for a primary stem cell transplant, Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, Patient must not be receiving concomitant PBS-subsidised bortezomib. 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 of 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. Thalidomide treatment failure is defined as: (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment. Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			daily living. Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity. Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as: (1) less than a 25% reduction in serum or urine M protein; or (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels. If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and (3) duration of thalidomide and daily dose prescribed; and (4) a signed patient acknowledgment. To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e),	

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			(f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.	
	C4091		Where the patient is receiving treatment at/from a private or public hospital Multiple myeloma Continuing PBS-subsidised treatment Patient must have previously received an authority prescription for lenalidomide, Patient must not have progressive disease, The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Patients receiving lenalidomide under the PBS listing must be registered in the access risk management program.	Compliance with modified Authority Required procedures
	C4282		Where the patient is receiving treatment at/from a private or public hospital Myelodysplastic syndrome Treatment Phase: Continuing treatment Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS) Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide Patient must not have progressive disease Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone The following evidence of response must be provided at each application: (i) a haemoglobin level taken within the last 4 weeks; and (ii) the date of the last transfusion; and (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and (iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.	
	C4287		Where the patient is receiving treatment at/from a private or public hospital Myelodysplastic syndrome Treatment Phase: Initial treatment The treatment must be limited to a maximum duration of 16 weeks Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS) Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities Patient must be red blood cell transfusion dependent Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations: 1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR 2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias. Classification of a patient as red blood cell transfusion dependent requires that: (i) the patient has been transfused within the last 8 weeks; and (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (d) a copy of the full blood examination report; and (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and (g) a signed patient acknowledgement form.	
Lenograstim	C1005		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures
	C1046		Where the patient is receiving treatment at/from a private hospital Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C1051		Where the patient is receiving treatment at/from a private hospital Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.	Compliance with Written or Telephone Authority Required procedures
	C1097		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma	Compliance with Written or Telephone Authority Required procedures
	C1140		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures
	C1168		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures
	C1228		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy;	Compliance with Written or Telephone Authority Required procedures
	C1238		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures
	C1240		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)	Compliance with Written or Telephone Authority Required procedures
	C1249		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma	Compliance with Written or Telephone Authority Required procedures
	C1274		Where the patient is receiving treatment at/from a private hospital Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation;	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C1324		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease	Compliance with Written or Telephone Authority Required procedures
	C1333		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma	Compliance with Written or Telephone Authority Required procedures
	C1555		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors;	Compliance with Written or Telephone Authority Required procedures
	C3392		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3392
	C3393		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3393
	C3394		Where the patient is receiving treatment at/from a public hospital Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3394
	C3395		Where the patient is receiving treatment at/from a public hospital Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3395

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3396		Where the patient is receiving treatment at/from a public hospital Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3396
	C3397		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3397
	C3398		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3398
	C3399		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3399
	C3400		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3400
	C3401		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3401
	C3402		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3402

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	C3403		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3403
	C3404		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3404
	C3405		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3405
Levodopa with carbidopa	C6154	P6154	Where the patient is receiving treatment at/from a private hospital Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic.	Compliance with Authority Required procedures
	C6179	P6179	Where the patient is receiving treatment at/from a public hospital Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic.	Compliance with Authority Required procedures - Streamlined Authority Code 6179
Lopinavir with ritonavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Macitentan	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.	Compliance with modified Authority Required procedures

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			A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	
	C6074	P6074	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients) Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. A maximum of 5 repeats will be authorised. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
	C6089	P6089	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	
	C6102	P6102	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6115	P6115	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology); AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
Mannitol	C5658	P5658	Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND Patient must be intolerant or inadequately responsive to dornase alfa. Patient must be 6 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	
	C5799	P5799	Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND Patient must be intolerant or inadequately responsive to dornase alfa. Patient must be 6 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5799

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Maraviroc	C5008		HIV infection Patient must be infected with CCR5-tropic HIV-1, AND The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5008
Methoxy polyethylene glycol-epoetin beta	C6260		Where the patient is receiving treatment at/from a private hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures
	C6294		Where the patient is receiving treatment at/from a public hospital Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
Mycophenolic Acid	C4084		Where the patient is receiving treatment at/from a public hospital Prophylaxis of renal allograft rejection Management The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required Procedures – Streamlined Authority Code 4084
	C4095		Where the patient is receiving treatment at/from a public hospital WHO Class III, IV or V lupus nephritis Management The condition must be proven by biopsy, Must be treated by a nephrologist or in consultation with a nephrologist. The name of the consulting nephrologist must be included in the patient medical records.	Compliance with Written or Telephone Authority Required Procedures – Streamlined Authority Code 4095

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4108		Where the patient is receiving treatment at/from a private hospital Prophylaxis of renal allograft rejection Management The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required Procedures
	C4146		Where the patient is receiving treatment at/from a private hospital WHO Class III, IV or V lupus nephritis Management The condition must be proven by biopsy, Must be treated by a nephrologist or in consultation with a nephrologist. The name of the consulting nephrologist must be included in the patient medical records	Compliance with Written or Telephone Authority Required Procedures
	C5554	P5554	Where the patient is receiving treatment at/from a public hospital Management of cardiac allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5554
	C5555	P5555	Where the patient is receiving treatment at/from a private hospital Management of cardiac allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5600	P5600	Where the patient is receiving treatment at/from a public hospital Management of cardiac allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5600
	C5601	P5601	Where the patient is receiving treatment at/from a private hospital Management of cardiac allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5626	P5626	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5653	P5653	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5653
	C5794	P5794	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5795	P5795	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5795
Natalizumab	C5987	P5987	Where the patient is receiving treatment at/from a private hospital Clinically definite relapsing-remitting multiple sclerosis Initial treatment The treatment must be as monotherapy; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older. Must be treated by a neurologist. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.	
	C6012	P6012	Where the patient is receiving treatment at/from a private hospital Clinically definite relapsing-remitting multiple sclerosis Continuing treatment The treatment must be as monotherapy; AND Patient must have previously been issued with an authority prescription for this drug; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must have demonstrated compliance with, and an ability to tolerate, this therapy. Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.	Compliance with Written or Telephone Authority Required procedures
	C6043	P6043	Where the patient is receiving treatment at/from a public hospital Clinically definite relapsing-remitting multiple sclerosis The treatment must be as monotherapy; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. Patient must be aged 18 years or older. Must be treated by a neurologist. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 6043

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.	
Nevirapine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
	C4526		HIV infection Initial treatment Patient must have been stabilised on nevirapine immediate release; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4526
Octreotide	C2622		Where the patient is receiving treatment at/from a private hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C2623		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour or VIPoma Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures
	C3407		Where the patient is receiving treatment at/from a public hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3407
	C3408		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour or VIPoma Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3408

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5896		Where the patient is receiving treatment at/from a private hospital Acromegaly The condition must be controlled with octreotide immediate release injections, AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures
	C5899		Where the patient is receiving treatment at/from a private hospital Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures
	C5900		Where the patient is receiving treatment at/from a public hospital Acromegaly The condition must be controlled with octreotide immediate release injections, AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5900
	C5901		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5901

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			to determine the minimum effective dose.	
	C5906		Where the patient is receiving treatment at/from a public hospital Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5906
	C5910		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures
Omalizumab	C4875	P4875	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.	Compliance with modified Authority Required procedures
	C4879	P4879	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Initial treatment - balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.	
	C4880	P4880	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma - Continuing treatment Patient must have a documented history of severe allergic asthma, AND Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline. All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.	
	C6142	P6142	Where the patient is receiving treatment at/from a private or public hospital Uncontrolled severe allergic asthma Initial treatment Patient must be under the care of the same physician for at least 12 months; AND Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; AND Patient must have past or current evidence of atopy, documented by skin prick testing or RAST; AND Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; AND Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be aged 12 years or older.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Optimised asthma therapy includes: (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. The initial IgE assessment must be no more than 12 months old at the time of application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the signed patient acknowledgement; and (c) the IgE pathology report; and (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.	
Pamidronic Acid	C4430		Where the patient is receiving treatment at/from a private hospital Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy	Compliance with Written and Telephone Authority Required procedures
	C4433		Where the patient is receiving treatment at/from a public hospital Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy	Compliance with Written and Telephone Authority Required procedures – Streamlined Authority Code 4433
	C5218		Where the patient is receiving treatment at/from a public hospital Multiple Myeloma	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5218
	C5256		Where the patient is receiving treatment at/from a private hospital Multiple Myeloma	Compliance with Written and Telephone Authority Required procedures
	C5257		Where the patient is receiving treatment at/from a private hospital	Compliance with Written and

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Bone metastases The condition must be due to breast cancer.	Telephone Authority Required procedures
	C5291		Where the patient is receiving treatment at/from a public hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5291
Paritaprevir with ritonavir with ombitasvir and dasabuvir	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Written or Telephone Authority Required procedures
Paritaprevir with ritonavir with ombitasvir and dasabuvir and ribavirin	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Written or Telephone Authority Required procedures
	C5972	P5972	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks.	Compliance with Written or Telephone Authority Required procedures
Pegfilgrastim	C2912		Where the patient is receiving treatment at/from a private hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;	Compliance with Written or Telephone Authority Required procedures
	C2917		Where the patient is receiving treatment at/from a private hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C2918		Where the patient is receiving treatment at/from a private hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2919		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2923		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures
	C2924		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures
	C2925		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures
	C2926		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures
	C2927		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures
	C2928		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures
	C2929		Where the patient is receiving treatment at/from a private hospital	Compliance with Written or

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Telephone Authority Required procedures
	C2930		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures
	C3087		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C3187		Where the patient is receiving treatment at/from a private hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.	Compliance with Written or Telephone Authority Required procedures
	C3357		Where the patient is receiving treatment at/from a public hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3357
	C3362		Where the patient is receiving treatment at/from a public hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3362

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3363		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3363
	C3364		Where the patient is receiving treatment at/from a public hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3364
	C3365		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3365
	C3369		Where the patient is receiving treatment at/from a public hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3369
	C3370		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3370
	C3371		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
				Authority Code 3371
	C3372		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3372
	C3373		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3373
	C3374		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3374
	C3375		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3375
	C3376		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3376
	C3377		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3377
	C3833		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3834		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3834
Peginterferon alfa-2a	C5004		Where the patient is receiving treatment at/from a public hospital Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Chronic hepatitis C infection Patient must have compensated liver disease, AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND Patient must have a contraindication to ribavirin, AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND The treatment must be limited to a maximum duration of 48 weeks. Population criteria: Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age. Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5004
	C5010		Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must not have previously received peginterferon alfa therapy for the treatment of hepatitis B, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 5010

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy, AND The treatment must be the sole PBS-subsidised therapy for this condition.	
	C5016		Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must not have previously received peginterferon alfa therapy for the treatment of hepatitis B, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy, AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Written and Telephone Authority Required procedures
	C5067	P5067	Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA, AND The treatment must be the sole PBS-subsidised therapy for this condition, AND The treatment must be limited to 1 course of treatment for a maximum duration of 48 weeks. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5067
Plerixafor	C4549		Where the patient is receiving treatment at/from a public hospital Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; OR Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4549

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have failed previous stem cell collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records	
	C4550		Where the patient is receiving treatment at/from a private hospital Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; OR Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND Patient must have failed previous stem cell collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Pomalidomide	C5101	P5101	Where the patient is receiving treatment at/from a private or public hospital This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment. Multiple myeloma Initial treatment The treatment must be in combination with dexamethasone, AND Patient must have undergone or be ineligible for a primary stem cell transplant, AND Patient must have experienced treatment failure with lenalidomide, AND Patient must have experienced treatment failure with bortezomib, AND Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide. 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 of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C5102	P5102	Where the patient is receiving treatment at/from a private or public hospital This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment. Multiple myeloma Continuing treatment Patient must have previously been issued with an authority prescription for this drug, AND Patient must not have progressive disease, AND The treatment must be in combination with dexamethasone, AND Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib. 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 of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Raltegravir	C4274		HIV infection Continuing treatment The treatment must be in combination with other antiretroviral agents, Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, Patient must have previously received PBS-subsidised therapy for HIV infection, Patient must be aged 2 years or older	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4274
	C4275		HIV infection Initial treatment The treatment must be in combination with other antiretroviral agents, Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease, Patient must be aged 2 years or older	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4275
	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Ribavirin	C5957	P5957	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5958	P5958	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks. Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.	Compliance with Written or Telephone Authority Required procedures
Ribavirin and Peginterferon Alfa-2a	C4184		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4184

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be	

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			documented in the patient's medical records	
	C4185		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary	
	C4187		Where the patient is receiving treatment at/from a public hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis; AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4187

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24. Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12 For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed	
	C4188		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	
	C4193		Where the patient is receiving treatment at/from a private hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	Compliance with Written or Telephone Authority Required procedures
	C4197		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4197

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary	
	C4206		Where the patient is receiving treatment at/from a public hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4206

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4207		Where the patient is receiving treatment at/from a private hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis; AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12 For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed	Compliance with Written or Telephone Authority Required procedures
	C5956	P5956	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be limited to a maximum duration of 12 weeks. Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.	
Ribavirin and Peginterferon Alfa-2b	C4184		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4184

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	
	C4185		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary	
	C4187		Where the patient is receiving treatment at/from a public hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis; AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4187

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12 For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed	
	C4188		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24	

Corrected Authorised Version registered 31/10/2016 F2016C00679

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	
	C4189		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12 Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4189
	C4192		Where the patient is receiving treatment at/from a public hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4192

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			hepatic cirrhosis or bridging fibrosis; AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12 For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed	
	C4193		Where the patient is receiving treatment at/from a private hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	
	C4197		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4197

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary	
	C4198		Where the patient is receiving treatment at/from a public hospital Chronic genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4198

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary	
	C4199		Where the patient is receiving treatment at/from a public hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12 Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4199
	C4200		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12. Patient must weigh at least 27 kg; AND	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	
	C4203		Where the patient is receiving treatment at/from a private hospital Chronic genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary	Compliance with Written or Telephone Authority Required procedures
	C4206		Where the patient is receiving treatment at/from a public hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4206

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	
	C4207		Where the patient is receiving treatment at/from a private hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis; AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed	
	C4208		Where the patient is receiving treatment at/from a private hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated); AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be limited to a maximum duration of 48 weeks; AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12 Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records	Compliance with Written or Telephone Authority Required procedures
	C4209		Where the patient is receiving treatment at/from a private hospital Chronic non-genotype 1 hepatitis C infection The treatment must be the sole PBS-subsidised treatment for hepatitis C; AND Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C; AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis; AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24 Patient must weigh at least 27 kg; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age Must be treated in an accredited treatment centre Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12 For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed	
Rifabutin	C1299		Where the patient is receiving treatment at/from a private hospital Prophylaxis against Mycobacterium avium complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1435		Where the patient is receiving treatment at/from a private hospital Treatment of Mycobacterium avium complex infections in human immunodeficiency virus-positive patients	Compliance with Written or Telephone Authority Required procedures
	C3317		Where the patient is receiving treatment at/from a public hospital Prophylaxis against Mycobacterium avium complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3317
	C3415		Where the patient is receiving treatment at/from a public hospital Treatment of Mycobacterium avium complex infections in human immunodeficiency virus-positive patients	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3415

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Rilpivirine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Ritonavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Rituximab	C5821	P5821	Where the patient is receiving treatment at/from a private or public hospital Severe active microscopic polyangiitis Induction of remission The treatment must be for the induction of remission; AND Patient must not have previously received this drug for this condition; OR Patient must have received this drug for this condition prior to 1 January 2016; AND The treatment must in combination with glucocorticoids; AND Patient must be at risk of end-organ damage or mortality; AND Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide. Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology. This drug is not PBS-subsidised for maintenance therapy.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5864	P5864	Where the patient is receiving treatment at/from a private or public hospital Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Re-induction of remission The treatment must be for the re-induction of remission; AND Patient must have previously received and responded to this drug for this condition; AND The treatment must in combination with glucocorticoids; AND Patient must be at risk of end-organ damage or mortality; AND Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide. Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology. This drug is not PBS-subsidised for maintenance of remission	Compliance with modified Authority Required procedures
	C5872	P5872	Where the patient is receiving treatment at/from a private or public hospital Severe active microscopic polyangiitis Re-induction of remission The treatment must be for the re-induction of remission; AND Patient must have previously received and responded to this drug for this condition; AND The treatment must in combination with glucocorticoids; AND Patient must be at risk of end-organ damage or mortality; AND Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide. Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology. This drug is not PBS-subsidised for maintenance therapy.	Compliance with modified Authority Required procedures
	C5895	P5895	Where the patient is receiving treatment at/from a private or public hospital Severe active granulomatosis with polyangiitis (Wegeners granulomatosis) Induction of remission The treatment must be for the induction of remission; AND Patient must not have previously received this drug for this condition; OR Patient must have received this drug for this condition prior to 1 January 2016; AND The treatment must in combination with glucocorticoids; AND Patient must be at risk of end-organ damage or mortality; AND Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology. This drug is not PBS-subsidised for maintenance of remission	
	C6015	P6015	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Continuing treatment Patient must have a documented history of severe active rheumatoid arthritis; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition; AND Patient must not receive more than 2 infusions of rituximab under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. The authority application must be made in writing and must include: (a) completed authority prescription form(s); and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. An adequate response to treatment is defined as:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C6042	P6042	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months). Patient must have a documented history of severe active rheumatoid arthritis; AND Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist; AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy; AND Patient must not receive more than 2 infusions of rituximab under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. The authority application must be made in writing and must include: (a) completed authority prescription form(s); and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment. A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C6049	P6049	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months) Patient must have severe active rheumatoid arthritis; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist; AND Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; AND Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 2 infusions of rituximab under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept,	

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			golimumab, infliximab, rituximab, tocilizumab or tofacitinib. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response	
Romiplostim	C3851		Where the patient is receiving treatment at/from a private or public hospital Initial (new patients) Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is: (1) Splenectomised and: (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy; or (2) Not splenectomised and: (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and (c) in whom splenectomy is contraindicated for medical reasons The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application: (a) a platelet count of less than or equal to 20,000 million per L; or	Compliance with modified Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a signed patient acknowledgement, (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. The full blood count must be no more than 1 month old at the time of application. At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone. The dose (microgram/kg/week) must be provided at the time of application. Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	
	C3852		Where the patient is receiving treatment at/from a private or public hospital Initial (previous treatment with Romiplostim not PBS-subsidised) Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with Romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			demonstrated to have been met at the time Romiplostim was commenced. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a signed patient acknowledgement, (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, and (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. For patients whose dose of Romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Where the patient is in the titration phase of treatment with Romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone. The dose (microgram/kg/week) must be provided at the time of application. Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	
	C3853		Where the patient is receiving treatment at/from a private or public hospital Continuing therapy or re-initiation after a break in therapy First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment with Romiplostim during the initial period of PBS-subsidised treatment. For the purposes of this restriction, a sustained platelet response is defined as use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised Romiplostim, and either of the following: (a) a platelet count greater than or equal to 50,000 million per L on at least four occasions, each at least one week apart; or (b) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four occasions, each at least one week apart. Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: (1) a completed authority prescription form, (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The most recent platelet count must be no more than one month old at the time of application. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	
	C3854		Where the patient is receiving treatment at/from a private or public hospital Second and subsequent applications for continuing therapy Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with Romiplostim and who continues to display a response to treatment with Romiplostim.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For the purposes of this restriction, a continuing response to treatment with Romiplostim is defined as use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with Romiplostim, and either of the following: (a) a platelet count greater than or equal to 50,000 million per L; or (b) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	
Saquinavir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Sevelamer	C5454	P5454	Where a patient is receiving treatment at/from a private hospital Hyperphosphataemia Treatment Phase: Initiation and stabilisation The condition must not be adequately controlled by calcium,AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. reatment criteria: Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Written or Telephone Authority Required procedures
	C5530	P5530	Where a patient is receiving treatment at/from a public hospital Hyperphosphataemia Treatment Phase: Initiation and stabilisation The condition must not be adequately controlled by calcium, AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Treatment criteria: Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5530
Sildenafil	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	Compliance with modified Authority Required procedures
	C6085	P6085	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients)	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6086	P6086	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients) Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
	C6089	P6089	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	
	C6114	P6114	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate,	

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			ambrisentan, tadalafil, and macitentan. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
Simeprevir	C4669	P4669	Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C; AND The treatment must be in combination with peginterferon alfa and ribavirin; AND The treatment must be limited to a maximum duration of 12 weeks; AND The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater. Patient must be 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre. Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.	Compliance with Written or Telephone Authority Required procedures
	C4684	P4684	Chronic genotype 1 hepatitis C infection Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND The treatment must be in combination with peginterferon alfa and ribavirin; AND The treatment must be limited to a maximum duration of 12 weeks; AND The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Must be treated in an accredited treatment centre. Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.	
Sirolimus	C5794	P5794	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5795	P5795	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5795
Sofosbuvir	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Written or Telephone Authority Required procedures
	C5972	P5972	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks.	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Stavudine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Sucroferric oxyhydroxide	C5454	P5454	Where a patient is receiving treatment at/from a private hospital Hyperphosphataemia Treatment Phase: Initiation and stabilisation The condition must not be adequately controlled by calcium,AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. reatment criteria: Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Written or Telephone Authority Required procedures
	C5530	P5530	Where a patient is receiving treatment at/from a public hospital Hyperphosphataemia Treatment Phase: Initiation and stabilisation The condition must not be adequately controlled by calcium, AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Treatment criteria: Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5530

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Tacrolimus	C5569	P5569	Where the patient is receiving treatment at/from a public hospital Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5569
	C5602	P5602	Where the patient is receiving treatment at/from a private hospital Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Written or Telephone Authority Required procedures
Tadalafil	C6065	P6065	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) First Continuing treatment Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition; AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6066	P6066	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Subsequent Continuing treatment Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			condition; OR Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.	
	C6071	P6071	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 2 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
	C6089	P6089	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.	Compliance with modified Authority Required procedures
	C6112	P6112	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 3 (change or re-commencement of therapy for all patients)	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate,	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.	
	C6127	P6127	Where the patient is receiving treatment at/from a private or public hospital Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician at a designated hospital; AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			contraindication to such treatment exists; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. 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. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
Telbivudine	C4994		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must be nucleoside analogue naive, AND Patient must have detectable HBV DNA, AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4994

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	
	C4995		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must be nucleoside analogue naive, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4995
Tenofovir	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4476		Chronic hepatitis B Patient must have cirrhosis; AND Patient must be nucleoside analogue naïve; AND Patient must have detectable HBV DNA; AND The treatment must be the sole PBS-subsidised therapy for this condition Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4476
	C4489		Chronic hepatitis B Patient must not have cirrhosis; AND Patient must be nucleoside analogue naïve; AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4489

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			conjunction with documented hepatitis B infection; AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy; AND The treatment must be the sole PBS-subsidised therapy for this condition	
	C4490		Chronic hepatitis B Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4490
	C4510		Chronic hepatitis B Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4510
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Tenofovir with emtricitabine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Tenofovir with emtricitabine and efavirenz	C4470		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial treatment Patient must be antiretroviral treatment naïve	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4522
Tenofovir with emtricitabine, elvitegravir and cobicistat	C4470		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial treatment Patient must be antiretroviral treatment naïve	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4522
Tenofovir with emtricitabine and rilpivirine	C4470		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial treatment Patient must be antiretroviral treatment naïve	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4522

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Thalidomide	C1233		Where the patient is receiving treatment at/from a private hospital Multiple myeloma.	Compliance with Written or Telephone Authority Required procedures
	C3342		Where the patient is receiving treatment at/from a public hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3342
Tipranavir	C5764	P5764	HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, AND The treatment must be co-administered with 200 mg ritonavir twice daily, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5764
Tocilizumab	C4453	P4453	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Continuing Treatment – balance of supply Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures
	C4466	P4466	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months) Patient must have a documented history of severe active juvenile idiopathic arthritis; AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C4493	P4493	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) Patient must have severe active juvenile idiopathic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and (3) an acknowledgement signed by a parent or authorised guardian. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.	
	C4497	P4497	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Continuing Treatment – balance of supply Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above	Compliance with modified Authority Required procedures

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			restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	
	C4502	P4502	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply. Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures
	C4508	P4508	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Continuing treatment Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have demonstrated an adequate response to treatment with tocilizumab; AND Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. An adequate response to treatment is defined as:	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.	
	C4515	P4515	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			years; AND Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be	

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			eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.	
	C4521	P4521	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Continuing treatment Patient must have a documented history of severe active juvenile idiopathic arthritis; AND Patient must have demonstrated an adequate response to treatment with tocilizumab; AND Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.	
	C4541	P4541	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months) Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	
	C4542	P4542	Where the patient is receiving treatment at/from a private or public hospital Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment after break of less than 24 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	
	C4672	P4672	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply. Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with modified Authority Required procedures
	C4673	P4673	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Continuing Treatment – balance of supply. Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with modified Authority Required procedures
	C5976	P5976	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) Patient must have severe active rheumatoid arthritis; AND Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug	Compliance with modified Authority Required procedures

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			(bDMARD) for this condition in the previous 24 months; AND Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant	

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			contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.	

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			Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.	
	C5977	P5977	Where the patient is receiving treatment at/from a private or public hospital Systemic juvenile idiopathic arthritis Continuing treatment - balance of supply Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with modified Authority Required procedures
	C5979	P5979	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Continuing treatment Patient must have a documented history of severe active rheumatoid arthritis; AND Patient must have demonstrated an adequate response to treatment with tocilizumab; AND Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at	Compliance with modified Authority Required procedures

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			least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C6019	P6019	Where the patient is receiving treatment at/from a private or public hospital Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply	Compliance with modified Authority Required procedures

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			Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	
	C6020	P6020	Where the patient is receiving treatment at/from a private or public hospital Systemic juvenile idiopathic arthritis Continuing treatment Patient must have a documented history of systemic juvenile idiopathic arthritis; AND Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be	Compliance with modified Authority Required procedures

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			based on the baseline measurements of disease severity submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab. Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.	
	C6041	P6041	Where the patient is receiving treatment at/from a private or public hospital Systemic juvenile idiopathic arthritis Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) Patient must have a documented history of systemic juvenile idiopathic arthritis; AND Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with modified Authority Required procedures

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			Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab. An adequate response to treatment is defined as: (a) in a patient with polyarticular course disease: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%: - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). (b) in a patient with refractory systemic symptoms: (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or	

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			(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.	
	C6050	P6050	Where the patient is receiving treatment at/from a private or public hospital Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months). Patient must have a documented history of severe active rheumatoid arthritis; AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib. The authority application must be made in writing and must include: (a) completed authority prescription form(s); and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment	Compliance with modified Authority Required procedures

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			criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).	

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	C6053	P6053	Where the patient is receiving treatment at/from a private or public hospital Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) Patient must have been diagnosed with systemic juvenile idiopathic arthritis; AND Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; OR Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			destruction or bony overgrowth). The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application: (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following: (i) the date of assessment of severe active systemic juvenile idiopathic arthritis; (ii) details of prior treatment including dose and duration of treatment; (iii) pathology reports detailing CRP and platelet count where appropriate; and (3) an acknowledgement signed by a parent or authorised guardian. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.	

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			If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.	
Valaciclovir	C5939	P5939	Where the patient is receiving treatment at/from a private hospital Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	Compliance with Written or Telephone Authority Required procedures
	C5975	P5975	Where the patient is receiving treatment at/from a public hospital Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5975
Valganciclovir	C4980		Cytomegalovirus retinitis Patient must have HIV infection.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4980
	C4989		Where the patient is receiving treatment at/from a public hospital Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4989
	C5031		Where the patient is receiving treatment at/from a private hospital Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Written and Telephone Authority Required procedures
Vedolizumab	C5072	P5072	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Initial PBS-subsidised treatment (Grandfather patient) Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			2015, AND Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic or partial Mayo clinic baseline assessment is not available, AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be 18 years of age or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the date of commencement of this drug; and (iii) the signed patient acknowledgement. The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.	

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			Up to a maximum of 2 repeats will be authorised. 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.	
	C5073	P5073	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.	Compliance with modified Authority Required procedures
	C5085	P5085	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Change or Recommencement of treatment (initial 2) Patient must have a documented history of severe Crohn disease, AND	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.	

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			If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.	
	C5096	P5096	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Continuing treatment Patient must have previously been issued with an authority prescription for this drug for this condition, AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose. Up to a maximum of 2 repeats will be authorised.	Compliance with modified Authority Required procedures

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	C5099	P5099	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Initial treatment (new patient - initial 1) Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment; and (v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.	

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			Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.	
	C5104	P5104	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.	Compliance with modified Authority Required procedures

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			Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	
	C5107	P5107	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Initial treatment (new patient - Initial 1) Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and	Compliance with modified Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the signed patient acknowledgement. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.	
	C5121	P5121	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Initial PBS-subsidised treatment (Grandfather) Patient must have a documented history of severe Crohn disease, AND Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, AND	Compliance with modified Authority Required procedures

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Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have had a Crohn s Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, AND Patient must have an adequate response to this drug defined as a reduction in Crohn s Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment; and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase. A patient may qualify for PBS-subsidised treatment under this restriction once only.	
	C5127	P5127	Where the patient is receiving treatment at/from a private or public hospital Severe Crohn disease Continuing treatment Patient must have a documented history of severe Crohn disease, AND Patient must have previously been issued with an authority prescription for this drug for this condition, AND Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient. Patient must be aged 18 years or older. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application. If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised. If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.	
	C5591	P5591	Where the patient is receiving treatment at/from a private or public hospital Moderate to severe ulcerative colitis Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2) Patient must have previously been issued with an authority prescription for infliximab or vedolizumab for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Patient must be treated by a gastroenterologist (code 87); OR Patient must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Patient must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose. Up to a maximum of 2 repeats will be authorised. Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.	Compliance with modified Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Zidovudine	C4454		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial treatment Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4512
Zoledronic acid	C5605	P5605	Where the patient is receiving treatment at/from a public hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5605
	C5606	P5606	Where the patient is receiving treatment at/from a private hospital Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Written or Telephone Authority Required procedures
	C5676	P5676	Where the patient is receiving treatment at/from a private hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures
	C5677	P5677	Where the patient is receiving treatment at/from a private hospital Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Written or Telephone Authority Required procedures
	C5703	P5703	Where the patient is receiving treatment at/from a public hospital Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5703
	C5704	P5704	Where the patient is receiving treatment at/from a public hospital Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5704

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5735	P5735	Where the patient is receiving treatment at/from a public hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5735
	C5736	P5736	Where the patient is receiving treatment at/from a private hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written or Telephone Authority Required procedures

Schedule 3 Part 1—General statement for drugs for the treatment of hepatitis C

1 Criteria for eligibility for drugs for the treatment of chronic hepatitis C

The criteria for patient eligibility for drugs for the treatment of chronic hepatitis C are that:

(1) the patient is 18 years or older; and

(2) the patient has been assessed in accordance with paragraph 2 of this Part; and

(3) the patient is:

a. treated by a medical practitioner who is experienced in the treatment of patients with chronic hepatitis C infection and is:

i. a gastroenterologist; or

ii. a hepatologist; or

iii. an infectious diseases physician; or

b. treated in consultation with a medical practitioner who is experienced in the treatment of patients with chronic hepatitis C infection and who is:

i. a gastroenterologist; or

ii. a hepatologist; or

iii. an infectious diseases physician

2 Assessment of patient

For the purpose of subparagraph 1(2) of this Part, the patient has been assessed if the treating medical practitioner has:

(1) documented the following information in the patient's medical records:

a. evidence of chronic hepatitis C infection; and

b. evidence of the patient's hepatitis C virus genotype; and

(2) chosen a regimen in accordance with paragraph 3 of this Part; and

(3) collected the following information for the purposes of the authority application:

a. the patient's hepatitis C virus genotype; and

b. whether the patient is:

i. cirrhotic; or

ii. Non-cirrhotic

(4) In this paragraph, evidence of chronic hepatitis C infection is documentation of:

a. repeat test results showing antibody to hepatitis C virus (anti-HCV) positive; and

b. test result showing hepatitis C virus ribonucleic acid (RNA) positive

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3 Treatment regimen

For the purpose of subparagraph 2(2) of this Part, the treating medical practitioner has chosen a regimen in accordance with this paragraph if the patient:

(1) is a kind of patient mentioned for an Item in column 2 of the following table; and

(2) is to receive one of the regimens mentioned in column 3 of the same Item of the following table

Item	Kind of patient	Regimen
1	Patient: (a) with Genotype 1; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 8 weeks; or (b) LEDIPASVIR with SOFOSBUVIR for 12 weeks; or (c) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR for 12 weeks; or (f) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks.
2	Patient: (a) with Genotype 1; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 12 weeks; or (b) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (c) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR for 12 weeks; or (f) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks.

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Item	Kind of patient	Regimen
3	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is non-cirrhotic	SOFOSBUVIR and RIBAVIRIN for 12 weeks.
4	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and (c) who is non-cirrhotic	SOFOSBUVIR and RIBAVIRIN for 12 weeks.
5	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is non-cirrhotic	Either: (a) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (b) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.
6	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is non-cirrhotic	Either: (a) DACLATASVIR and SOFOSBUVIR for 12 weeks; or (b) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.
7	Patient: (a) with: (i) Genotype 4; or (ii) Genotype 5; or (iii) Genotype 6; and (b) who is treatment naïve; and (c) who is non-cirrhotic	SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.
8	Patient: (a) with: (i) Genotype 4; or (ii) Genotype 5; or (iii) Genotype 6; and (b) who is treatment experienced; and (c) who is non-cirrhotic	SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.

Item	Kind of patient	Regimen
9	Patient: (a) with Genotype 1; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 12 weeks; or (b) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (c) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks.
10	Patient: (a) with Genotype 1; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) LEDIPASVIR with SOFOSBUVIR for 24 weeks; or (b) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (c) DACLATASVIR and SOFOSBUVIR and RIBAVIRIN for 12 weeks; or (d) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks; or (e) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 12 weeks; or (f) PARITAPREVIR with RITONAVIR with OMBITASVIR and DASABUVIR and RIBAVIRIN for 24 weeks.
11	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is cirrhotic	SOFOSBUVIR and RIBAVIRIN for 12 weeks.

Item	Kind of patient	Regimen
12	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and (c) who is cirrhotic	SOFOSBUVIR and RIBAVIRIN for 12 weeks.
13	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is cirrhotic	Either: (a) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (b) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.
14	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is cirrhotic	Either: (a) DACLATASVIR and SOFOSBUVIR for 24 weeks; or (b) SOFOSBUVIR and RIBAVIRIN for 24 weeks; or (c) SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.
15	Patient: (a) with: (i) Genotype 4; or (ii) Genotype 5; or (iii) Genotype 6; and (b) who is treatment naïve; and (c) who is cirrhotic	SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.
16	Patient: (a) with: (i) Genotype 4; or (ii) Genotype 5; or (iii) Genotype 6; and (b) who is treatment experienced; and (c) who is cirrhotic	SOFOSBUVIR and PEGINTERFERON ALFA-2A with RIBAVIRIN for 12 weeks.

Schedule 4—Patient contributions

Listed Drug	Form (strength, type, size, etc.)	Manner of Administration	Brand	Pack Quantity	Approved Ex-manufacturer Price or Proportional Ex-manufacturer Price $	Claimed price $
Desferrioxamine	Powder for injection containing desferrioxamine mesylate 500 mg	Injection	Desferal 500 mg	10	81.02	87.74
	Powder for injection containing desferrioxamine mesylate 2 g	Injection	Desferal 2 g	1	32.40	32.73

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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 the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

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

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

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

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

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

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 116 of 2010	29 Nov 2010 (F2010L03140)	1 Dec 2010 (s 2)	
PB 122 of 2010	17 Dec 2010 (F2010L03308)	1 Jan 2010 (s 2)	—
PB 2 of 2011	31 Jan 2011 (F2011L00168)	1 Feb 2011 (s 2)	—
PB 16 of 2011	28 Feb 2011 (F2011L00316)	1 Mar 2011 (s 2)	—
PB 28 of 2011	31 Mar 2011 (F2011L00546)	1 Apr 2011 (s 2)	—
PB 34 of 2011	27 Apr 2011 (F2011L00643)	1 May 2011 (s 2)	—
PB 38 of 2011	31 May 2011 (F2011L00893)	1 June 2011 (s 2)	—
PB 46 of 2011	24 June 2011 (F2011L01221)	1 July 2011 (s 2)	—
PB 53 of 2011	27 July 2011 (F2011L01543)	1 Aug 2011 (s 2)	—
PB 62 of 2011	31 Aug 2011 (F2011L01777)	1 Sept 2011 (s 2)	—
PB 69 of 2011	28 Sept 2011 (F2011L01978)	1 Oct 2011 (s 2)	—
PB 76 of 2011	26 Oct 2011 (F2011L02130)	1 Nov 2011 (s 2)	—
PB 86 of 2011	30 Nov 2011 (F2011L02501)	1 Dec 2011 (s 2)	—
PB 99 of 2011	15 Dec 2011 (F2011L02694)	1 Jan 2011 (s 2)	—
PB 5 of 2012	23 Feb 2012 (F2012L00380)	1 Mar 2012 (s 2)	—
PB 20 of 2012	29 Mar 2012 (F2012L00716)	1 Apr 2012 (s 2)	—
PB 31 of 2012	30 Apr 2012 (F2012L00952)	1 May 2012 (s 2)	—
PB 35 of 2012	30 May 2012 (F2012L01122)	1 June 2012 (s 2)	—
PB 39 of 2012	29 June 2012 (F2012L01458)	1 July 2012 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 47 of 2012	26 July 2012 (F2012L01615)	1 Aug 2012 (s 2)	—
PB 64 of 2012	29 Aug 2012 (F2012L01783)	1 Sept 2012 (s 2)	—
PB 76 of 2012	28 Sept 2012 (F2012L01971)	1 Oct 2012 (s 2)	—
PB 96 of 2012	30 Oct 2012 (F2012L02107)	30 Oct 2012 (s 2)	—
PB 106 of 2012	29 Nov 2012 (F2012L02286)	1 Dec 2012 (s 2)	—
PB 110 of 2012	17 Dec 2012 (F2012L02508)	1 Jan 2013 (s 2)	—
PB 10 of 2013	21 Feb 2013 (F2013L00245)	1 Mar 2013 (s 2)	—
PB 16 of 2013	27 Mar 2013 (F2013L00562)	1 Apr 2013 (s 2)	—
PB 30 of 2013	30 May 2013 (F2013L00874)	1 June 2013 (s 2)	—
PB 42 of 2013	31 July 2013 (F2013L01483)	1 Aug 2013 (s 2)	—
PB 56 of 2013	27 Aug 2013 (F2013L01630)	1 Sept 2013 (s 2)	—
PB 63 of 2013	24 Sept 2013 (F2013L01736)	1 Oct 2013 (s 2)	—
PB 70 of 2013	18 Oct 2013 (F2013L01812)	1 Nov 2013 (s 2)	—
PB 78 of 2013	29 Nov 2013 (F2013L02011)	1 Dec 2013 (s 2)	—
PB 92 of 2013	24 Dec 2013 (F2013L02191)	1 Jan 2014 (s 2)	—
PB 4 of 2014	28 Jan 2014 (F2014L00098)	1 Feb 2014 (s 2)	—
PB 11 of 2014	25 Feb 2014 (F2014L00183)	1 Mar 2014 (s 2)	—
PB 20 of 2014	31 Mar 2014 (F2014L00372	1 Apr 2014 (s 2)	—
PB 30 of 2014	29 Apr 2014 (F2014L00449)	1 May 2014 (s 2)	—
PB 40 of 2014	21 May 2014 (F2014L00577)	1 June 2014 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 48 of 2014	20 June 2014 (F2014L00766)	1 July 2014 (s 2)	—
PB 55 of 2014	31 July 2014 (F2014L01065)	1 Aug 2014 (s 2)	—
PB 63 of 2014	25 Aug 2014 (F2014L01126)	1 Sept 2014 (s 2)	—
PB 93 of 2014	1 Dec 2014 (F2014L01610)	1 Dec 2014 (s 2)	—
PB 102 of 2014	24 Dec 2014 (F2014L01834)	1 Jan 2015 (s 2)	—
PB 3 of 2015	30 Jan 2015 (F2015L00087)	1 Feb 2015 (s 2)	—
PB 30 of 2015	1 Apr 2015 (F2015L00457)	1 Apr 2015 (s 2)	—
PB 43 of 2015	29 Apr 2015 (F2015L00607)	1 May 2015 (s 2)	—
PB 50 of 2015	1 June 2015 (F2015L00770)	1 June 2015 (s 2)	—
PB 58 of 2015	1 July 2015 (F2015L01073)	1 July 2015 (s 2)	—
PB 72 of 2015	31 July 2015 (F2015L01214)	1 Aug 2015 (s 2)	—
PB 83 of 2015	1 Sept 2015 (F2015L01370)	1 Sept 2015 (s 2)	—
PB 94 of 2015	1 Oct 2015 (F2015L01619)	1 Oct 2015 (s 2)	—
PB 104 of 2015	30 Oct 2015 (F2015L01723)	1 Nov 2015 (s 2)	—
PB 111 of 2015	1 Dec 2015 (F2015L01908)	1 Dec 2015 (s 2)	—
PB 121 of 2015	18 Dec 2015 (F2015L02085)	18 Dec 2015 (s 2)	—
PB 129 of 2015	24 Dec 2015 (F2015L02138)	1 Jan 2016 (s 2)	—
PB 5 of 2016	1 Feb 2016 (F2016L00076)	1 Feb 2016 (s 2)	—
PB 13 of 2016	1 Mar 2016 (F2016L00216)	1 Mar 2016 (s 2)	—
PB 22 of 2016	1 Apr 2016 (F2016L00473)	1 Apr 2016 (s 2)	—
PB 33 of 2016	29 Apr 2016 (F2016L00607)	1 May 2016 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 45 of 2016	31 May 2016 (F2016L00924)	1 June 2016 (s 2)	—
PB 55 of 2016	28 June 2016 (F2016L01091)	1 July 2016 (s 2)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
Division 1	
s 1	am PB 58 of 2015
s 4	am PB 122 of 2010; PB 2, 16, 28, 46, 62 and 99 of 2011; PB 20, 31, 35, 39 and 76 of 2012; PB 20, 63 and 93 of 2014; PB 3, 30 and 58 of 2015; PB 72 of 2015 (md Sch 1 item 1); PB 33 of 2016
Division 2	
s 9A	ad PB 93 of 2014
Division 3	
Division 3 heading	rs PB 30 of 2015
Division 3	am PB 30 of 2015
s 10	am PB 62 of 2011; PB 30 of 2015; PB 33 of 2016
s 11	am PB 62 of 2011
	rep PB 30 of 2015
s 12	am PB 62 of 2011
	rep PB 30 of 2015
s 13	am PB 62 of 2011
	rep PB 30 of 2015
Part 2	
Division 1	
s 17A	ad PB 93 of 2014
s 18	am PB 30 and 58 of 2015
	rs PB 33 of 2016
s 18A	ad PB 58 of 2015
Division 2	
s 19	am PB 30 an 58 of 2015
Division 3	
s 21	am PB 30 of 2015
s 22	rep PB 30 of 2015
s 22A	ad PB 93 of 2014
Division 4	
s 23	am PB 30 of 2015
s 23A	ad PB 93 of 2014
s 24	am PB 2, 28, 46 and 99 of 2011; PB 5, 20 and 31 of 2012
	rs PB 63 of 2013
s 25	am PB 2, 28, 46 and 99 of 2011; PB 20 and 31 of 2012
	rs PB 63 of 2013

Endnote 4—Amendment history

Provision affected	How affected
s 26	rs PB 30 of 2015
Part 3	rep PB 30 of 2015
s 27	rep PB 30 of 2015
Part 4	
Division 1	rep PB 30 of 2015
s 28	am PB 62 of 2011; PB 76 of 2012
	rep PB 30 of 2015
s 29	rep PB 30 of 2015
Division 2	
Subdivision 1	
s 30	am PB 30 of 2015
Subdivision 2	rep PB 30 of 2015
s 32	rep PB 30 of 2015
s 33	am PB 39 of 2012
	rep PB 30 of 2015
s 34	rep PB 30 of 2015
Division 3	
Division 3 heading	am PB 58 of 2015
s 36	am PB 58 of 2015
Part 5	
Division 1	
s 37	am PB 76 and 96 of 2012
s 38	rs PB 76 of 2012
Division 2	
Division 2 heading	am PB 58 of 2015
s 39	am PB 122 of 2010; PB 76 of 2012; PB 58 of 2015
s 40	am PB 76 and 96 of 2012
s 41	rs PB 76 of 2012
Division 3	
s 43	am PB 122 of 2010
	rep PB 76 of 2012
Part 6	
s 45	am PB 122 of 2010; PB 5 and 106 of 2012
	rep PB 30 of 2015
s 46	am PB 106 of 2012; PB 30 of 2015
s 47	am PB 106 of 2012; PB 30 and 58 of 2015
s 48	am PB 76 of 2012
	rs PB 106 of 2012

Endnote 4—Amendment history

Provision affected	How affected
	am PB 30 of 2015
Part 7	
s 49	am PB 62 of 2011
	rs PB 58 of 2015
s 50	am PB 30 and 58 of 2015
s 51	am PB 20 of 2012; PB 30 and 58 of 2015
Part 8	
s 52	am PB 62 of 2011
Part 9	
s 54	rep PB 30 of 2015
	ad PB 30 of 2015
s 55	rep PB 30 of 2015
	ad PB 30 of 2015
s 56	ad PB 58 of 2015
Schedule 1	
Schedule 1	am PB 122 of 2010; PB 2, 28, 34, 38, 46, 53, 62, 69, 76, 86 and 99 of 2011; PB 5, 20, 31, 35, 39, 47, 64, 76, 106 and 110 of 2012; PB 10, 16, 30, 42, 56, 63, 70, 78 and 92 of 2013; PB 4, 11, 20, 30, 40, 48, 55, 63, 93 (md items 13, 14) and 102 of 2014; PB 3, 30, 43, 50, 58, 72, 83, 94, 104, 111, 121 and 129 of 2015; PB 5, 13 and 22 of 2016 (md sch 1 items 1-3, 6); PB 33, 45 and 55 of 2016
Schedule 2	
Schedule 2	am PB 122 of 2010; PB 34, 46, 53 and 69 of 2011; PB 5, 20, 31, 47, 76, 106 and 110 of 2012; PB 16 of 2013
	rs PB 63 of 2013
	am PB 11, 93 and 102 of 2014; PB 30, 72, 94 and 104 of 2015; PB 5 and 22 of 2016
Schedule 3	
Schedule 3	am PB 122 of 2010; PB 16, 28, 34, 38, 46, 62, 76, 86 and 99 of 2011; PB 5, 20, 31, 35, 39, 47 and 106 of 2012; PB 16, 56, 63, 70, 78 and 92 of 2013; PB 4, 20, 30, 40, 48, 63 and 93 (md item 24) of 2014; PB 3, 30, 43, 50, 58, 72, 83.94, 104, 111, 121 and 129 of 2015; PB 5, 13, 22, 33, 45 and 55 of 2016
Part 1	
s 1	ad PB 13 of 2016
s 2	ad PB 13 of 2016
s 3	ad PB 13 of 2016
Schedule 4	
Schedule 4	am PB 28 of 2011
	rs PB 38 of 2011
	am PB 47 of 2012
	rs PB 76 of 2012; PB 16 of 2013