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

made under subsections 100(1) and (2) 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 November 2020 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

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.

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, or an authorised nurse 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, or an authorised nurse 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, or an authorised nurse 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*.

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

authorised prescriber has the meaning given by section 4A.

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) benralizumab
(f) bosentan
(g) eculizumab
(h) eltrombopag
(i) epoprostenol

(j) etanercept
(k) iloprost
(l) infliximab
(m) ivacaftor
(n) lenalidomide
(o) lumacaftor with ivacaftor
(p) macitentan
(q) mepolizumab
(r) midostaurin
(s) nusinersen
(t) omalizumab
(u) pasireotide
(v) pegvisomant
(w) pomalidomide
(x) riociguat
(y) rituximab
(z) romiplostim
(aa) sildenafil
(bb) tadalafil
(cc) teduglutide
(dd) tezacaftor with ivacaftor and ivacaftor
(ee) tocilizumab
(ff) ustekinumab
(gg) 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
(bb) who is, for the prescription of medication for the treatment of schizophrenia—an accredited prescriber of medication for the treatment of schizophrenia; 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.

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

(b) entecavir
(c) interferon alfa-2a
(e) lamivudine
(g) tenofovir

medication for the treatment of hepatitis C means medication mentioned in the table in paragraph 3 of the General Statement for drugs for the treatment of hepatitis C.

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

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

(hh) tenofovir with emtricitabine
(ii) tenofovir with emtricitabine and efavirenz
(jj) tipranavir
(kk) valganciclovir
(ll) 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.

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 Benefit) Regulations 2017*.

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.

4A Definition of *authorised prescriber*

(1) An eligible medical practitioner for the prescription of an HSD pharmaceutical benefit under this Special Arrangement to an eligible patient is an ***authorised prescriber*** for the HSD pharmaceutical benefit.

(2) A medical practitioner is an ***authorised prescriber*** for each of the following HSD pharmaceutical benefits for the purpose of the treatment of hepatitis C:

(a) grazoprevir with elbasvir;

(b) ledipasvir with sofosbuvir; and

(c) ribavirin.

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

Authorised prescribers for certain HSD pharmaceutical benefits

Item	Column 1 Person	Column 2 HSD pharmaceutical benefit
1	An accredited prescriber of medication for the treatment of hepatitis B	A medication for the treatment of hepatitis B
2	An accredited prescriber of medication for the treatment of hepatitis C	A medication for the treatment of hepatitis C
3	An accredited prescriber of medication for the treatment of HIV or AIDS	A medication for the treatment of HIV or AIDS

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

Note: 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.

8 Prescribing of HSD pharmaceutical benefits—authorised prescribers

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

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

(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 9(1A) of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (which provides for the pharmaceutical benefits for which medical practitioners are authorised to write prescriptions) does not apply to an HSD pharmaceutical benefit other than a medication for the treatment of hepatitis C.

(6) Subsection (1) does not apply to an HSD pharmaceutical benefit mentioned in Part 2 of Schedule 1 to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (ready-prepared pharmaceutical benefits for supply only).

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.

(3) This section has effect subject to section 9AA (which temporarily modifies the circumstances mentioned in Schedule 3 for circumstances codes for HSD pharmaceutical benefits that are pharmaceutical items described in Schedule 5).

9AA Modified prescription circumstances during COVID-19 pandemic

(1) This section affects the circumstances in which a prescription may be written by an authorised prescriber for the supply of an HSD pharmaceutical benefit that is a listed brand of a pharmaceutical item described in Schedule 5 to a person (the ***patient***) if the authorised prescriber is satisfied the patient has, in accordance

with this Special Arrangement, already been supplied with the benefit on the basis of a prescription written in circumstances determined by subsection 9(1) unaffected by this section.

(2) For the purposes of subsection 9(1), Schedule 3 has effect as if each circumstances code for the HSD pharmaceutical benefit:

(a) did not mention any circumstance that, having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish in relation to the patient; and

(b) mentioned the circumstance that the authorised prescriber keeps a written record of the reason it is not practicable to establish the circumstance described in paragraph (a).

(3) This section, subsection 9(3) and Schedule 5 are repealed at the start of 1 April 2021.

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;

(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).

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.

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 authorised prescriber for the HSD pharmaceutical benefit 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: 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: 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.

15 Maximum number of repeats

(1) The maximum number of occasions an authorised prescriber for the HSD pharmaceutical benefit 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 authorised prescriber for the HSD pharmaceutical benefit 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.

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.

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;

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.

Division 2—Repeat prescriptions

19 Application of section 51 of the Regulations

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

20 No repeats for visitors

An authorised prescriber for an HSD pharmaceutical benefit must not write a repeat prescription for the 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.

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

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

An authorised prescriber for an HSD pharmaceutical benefit that has a non-CAR drug may prescribe the HSD pharmaceutical benefit under this Special Arrangement by:

(a) writing a prescription for the HSD pharmaceutical benefit in accordance with section 40 of the Regulations; or

(b) preparing a medication chart prescription for the HSD pharmaceutical benefit in accordance with section 41 of the Regulations.

Note: An authorised prescriber for an HSD pharmaceutical benefit that has a non-CAR drug may prescribe more than the maximum quantity, or more than the maximum number of repeats, of the HSD pharmaceutical benefit only in accordance with section 30 of the Regulations.

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

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

(a) authorised prescriber; 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.

Division 4—Prescribing HSD pharmaceutical benefits that have CAR drugs

23 Prescriptions for HSD pharmaceutical benefits that have CAR drugs

An authorised prescriber for an HSD pharmaceutical benefit that has a CAR drug may prescribe the HSD pharmaceutical benefit by writing a prescription for the HSD pharmaceutical benefit in accordance with section 40 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 authorised prescriber for an HSD pharmaceutical benefit referred to in section 9A prescribes the HSD pharmaceutical benefit for supply under Part VII of the Act, and the HSD pharmaceutical benefit has a CAR drug, then either the:

(a) authorised prescriber; 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 authorised prescriber for an HSD pharmaceutical benefit that has a CAR drug mentioned in subsection (2) may write a prescription for the HSD pharmaceutical benefit to be supplied to an eligible patient on any one occasion only in accordance with the limitation mentioned in subsection (2) for the drug.

(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;

(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;

(da) for HSD pharmaceutical benefits that have the drug infliximab, for the treatment of a patient with moderate to severe ulcerative colitis—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.

(db) for HSD pharmaceutical benefits that have the drug infliximab, for the treatment of an adult with severe 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.

(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;

(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.

(ra) for HSD pharmaceutical benefits that have the drug omalizumab, for the treatment of severe chronic spontaneous urticaria:

(i) for initial treatment—a quantity of units that are sufficient to provide for 12 weeks treatment;

(ii) for initial PBS-subsidised treatment in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfathered patients)—a quantity of units that are sufficient to provide for 24 weeks treatment;

(iii) 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;

—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.

(x) for HSD pharmaceutical benefits that have the drug riociguat, for the treatment of Chronic thromboembolic pulmonary hypertension (CTEPH):

(ii) for Initial treatment—prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily. Approvals for subsequent authority prescriptions will be limited to 1 month of treatment.

(iii) for Continuing treatment—the maximum quantity per prescription will be limited to provide sufficient supply for 1 month of treatment.

(y) for HSD pharmaceutical benefits that have the drug riociguat, for balance of supply for patient who has received insufficient therapy with this agent:

(ii) for Initial treatment—maximum of 20 weeks of treatment.

(iii) for Continuing treatment—maximum of 24 weeks of treatment—the treatment must provide no more than the balance up to 20 or 24 weeks of treatment available under the above respective restriction.

(z)for HSD pharmaceutical benefits that have the drug riociguat, for the treatment of Pulmonary arterial hypertension (PAH):

(i) for Initial 1(new patients), Initial 2 (new patients) and Initial 3 (change or re-commencement of therapy for all patients) – prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily. Approvals for subsequent authority prescriptions will be limited to 1 month of treatment.

(ii) for First Continuing treatment and Subsequent Continuing treatment – the maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment.

(iii) for Initial 1 (new patients) or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First

Continuing treatment – Balance of supply – the treatment must provide no more than the balance of up to six months treatment.

(za) for HSD pharmaceutical benefits that have the drug pasireotide, for the treatment of acromegaly:

(i) with the form Injection (modified release) 20 mg (as embonate), vial and diluent syringe—up to 2 vials and diluent syringes;

(ii) with the form Injection (modified release) 40 mg (as embonate), vial and diluent syringe—up to 2 vials and diluent syringes;

(iii) with the form Injection (modified release) 60 mg (as embonate), vial and diluent syringe—up to 2 vials and diluent syringes.

(zb) for HSD pharmaceutical benefits that have the drug pegvisomant, for the treatment of acromegaly:

(i) for initial treatment, for the 80 mg loading dose—4 x injection set containing powder for injection 20 mg, 1 and diluent, 1;

(ii) for initial treatment (subsequent doses)—1 x injection set containing powder for injection 10 mg, 15 mg or 20 mg, 30 and diluent, 30;

(iii) for initial PBS-subsidised treatment in a patient who has previously received non-PBS-subsidised therapy with pegvisomant—1 x injection set containing powder for injection 10 mg, 15 mg or 20 mg, 30 and diluent, 30;

(iv) for continuing treatment—1 x injection set containing powder for injection 10 mg, 15 mg or 20 mg, 30 and diluent, 30.

(zc) for HSD pharmaceutical benefits that have the drug ustekinumab, for the treatment of severe Crohn disease:

(i) for initial treatment, for a weight-based loading dose—up to 4 vials of Solution for I.V. infusion 130 mg in 26 mL;

(ii) for a change or re-commencement of treatment, for a weight-based loading dose—up to 4 vials of Solution for I.V. infusion 130 mg in 26 mL.

(zd) for HSD pharmaceutical benefits that have the drug vedolizumab, for the treatment of moderate to severe ulcerative colitis—the appropriate number of vials to provide for a single infusion of 300 mg per dose.

(ze) for HSD pharmaceutical benefits that have the drug vedolizumab, for the treatment of severe Crohn disease— the appropriate number of vials to provide for a single infusion of 300 mg.

(zf) for HSD pharmaceutical benefits that have the drug nusinersen, for PBS-subsidised treatment of spinal muscular atrophy:

(i) for initial treatment with loading doses at days 0, 14, 28 and 63—up to 2 x solution for injection 12 mg in 5 mL for days 0 and 14; up to 1 x solution for injection 12 mg in 5 mL for day 28 or 63.

(ii) for continuing treatment—0 repeat supplies

25 HSD pharmaceutical benefits that have CAR drugs—repeat exceptions

(1) An authorised prescriber for an HSD pharmaceutical benefit that has a CAR drug mentioned in subsection (2) may authorise the repeat supply of the HSD pharmaceutical benefit 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:

(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;

(ga) for infliximab, for the treatment of a patient with moderate to severe ulcerative colitis:

(i) for initial treatment (new patient or re-commencement of treatment after more than 5 years break in therapy)—up to 2 repeat supplies;
(ii) for a change or re-commencement of treatment after a break in therapy—up to 2 repeat supplies;
(iii) for continuing treatment—up to 2 repeat supplies.

(gb) for infliximab, for the treatment of an adult with severe Crohn disease:
(i) for initial treatment (new patient – initial 1)—up to 2 repeat supplies;
(ii) for a change or re-commencement of treatment (initial 2)—up to 2 repeat supplies;
(iii) for continuing treatment—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;

(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.

(va) for omalizumab, for the treatment of severe chronic spontaneous urticaria:
  (i) for initial treatment—where the patient has received a quantity of units that are sufficient to provide for 12 weeks treatment—0 repeat supplies;
  (ii) for initial PBS-subsidised treatment in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfathered patients)—where the patient has received a quantity of units that are sufficient to provide for 24 weeks treatment—0 repeat supplies;
  (iii) for continuing treatment—where the patient has received a quantity of units that are sufficient to provide for 24 weeks treatment—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 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.

(zb) for riociguat, for the treatment of Chronic thromboembolic pulmonary hypertension (CTEPH):

(ii) for initial treatment—up to 3 repeat supplies.

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

(zc) for riociguat, for the treatment of Pulmonary arterial hypertension (PAH):

(i) for Initial 1 (new patients), Initial 2 (new patients) and Initial 3 (change or re-commencement of therapy for all patients) – up to 4 repeat supplies.

(ii) for First Continuing treatment and Subsequent Continuing treatment – up to 5 repeat supplies.

(zd) for pasireotide—up to 5 repeat supplies.

(ze) for pegvisomant:

(i) for initial treatment, for the 80 mg loading dose—0 repeat supplies;

(ii) for intitial treatment (subsequent doses)—up to 5 repeat supplies;

(iii) for initial PBS-subsidised treatment in a patient who has previously received non-PBS-subsidised therapy with pegvisomant—up to 5 repeat supplies;

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

(zf) for ustekinumab:

(i) for initial treatment, for a weight-based loading dose—0 repeat supplies;

(ii) for a change or re-commencement of treatment, for a weight-based loading dose——0 repeat supplies.

(zg) for vedolizumab, for the treatment of severe Crohn disease:

(i) for initial treatment (new patient – initial 1)—up to 2 repeat supplies;

(ii) for a change or re-commencement of treatment (initial 2)—up to 2 repeat supplies;

(iii) for initial PBS-subsidised treatment (grandfather)—up to 2 repeat supplies;

(iv) for continuing treatment—up to 2 repeat supplies.

(zh) for vedolizumab, for the treatment of moderate to severe ulcerative colitis:

(i) for initial treatment (new patient – initial 1)—up to 2 repeat supplies;

(ii) for a change or re-commencement of treatment after a break in therapy (initial 2)—up to 2 repeat supplies;

(iii) for initial PBS-subsidised treatment (grandfather patient)—up to 2 repeat supplies;

(iv) for continuing treatment—up to 2 repeat supplies.

(zi) for nusinersen, for the treatment of spinal muscular atrophy:

(i) for initial treatment loading doses —up to 1 x solution for injection 12 mg in 5 mL

(ii) for continuing treatment—up to 1 x solution for injection 12 mg in 5 mL

(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 section 30 of the Regulations in relation to CAR drugs

Section 30 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.

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: 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.

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.

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.

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 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 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 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 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

(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 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 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

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 quantity of repeated supply directed to be supplied on one occasion

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

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

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.

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 section 16 includes a reference to a number allotted to an approval under:
  (i) subsection 52(3) of this Special Arrangement; and

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

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

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 Secretary 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 Secretary may, in writing, approve the hospital authority for this Special Arrangement.

(3) If the Secretary 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 subsection 16(4) 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 Secretary determines.

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

(7) The Secretary 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.

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 *National Health (Pharmaceutical Benefits) Regulations 1960* as in force immediately before the commencement 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.

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	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Abacavir	Tablet 300 mg (as sulfate)	Oral	Ziagen	VI	C4454 C4512		120	5	D
	Oral solution 20 mg (as sulfate) per mL, 240 mL	Oral	Ziagen	VI	C4454 C4512		8	5	D
Abacavir with Lamivudine	Tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg	Oral	Abacavir/Lamivudine GH 600/300	GQ	C4527 C4528		60	5	D
	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	ABACAVIR/ LAMIVUDINE 600/300 SUN	RA	C4527 C4528		60	5	D
			Abacavir/ Lamivudine Mylan	AF	C4527 C4528		60	5	D
			Kivexa	VI	C4527 C4528		60	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Abacavir with Lamivudine and Zidovudine	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	Oral	Trizivir	VI	C4480 C4495		120	5	D
Abatacept	Powder for I.V. infusion 250 mg	Injection	Orencia	BQ	C8627 C8638 C8655 C8688 C8748 C8759		See Note 1	See Note 2	PB
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Humira	VE	C9384 C9417 C10582 C10583 C10600 C10619		See Note 1	See Note 2	C
	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Humira	VE	C9384 C9417 C10582 C10583 C10600 C10619		See Note 1	See Note 2	C
	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Humira	VE	C9384 C9417 C10582 C10583 C10600 C10619		See Note 1	See Note 2	C

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Adefovir	Tablet containing adefovir dipivoxil 10 mg	Oral	APO-Adefovir	TX	C4490 C4510		60	5	D
Alemtuzumab	Solution concentrate for I.V. infusion 12 mg in 1.2 mL	Injection	Lemtrada	GZ	C6847 C7714 C9589 C9636	P6847 P9589	3	0	D
					C6847 C7714 C9589 C9636	P7714 P9636	5	0	D
Ambrisentan	Tablet 5 mg	Oral	Volibris	GK	C10228 C10236 C10285		See Note 1	See Note 2	D
	Tablet 10 mg	Oral	Volibris	GK	C10228 C10236 C10285		See Note 1	See Note 2	D
Anakinra	Injection 100 mg in 0.67 mL single use pre-filled syringe	Injection	Kineret	FK	C5450		28	5	D
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL	Injection	Movapo	TD	C4833 C9561		360	5	PB
	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	Injection	Movapo	TD	C4833 C9561		180	5	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	Apomine Solution for Infusion	PF	C10830 C10863		90	5	C
	Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe	Injection	Movapo PFS	TD	C4833 C9561		180	5	PB
	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Apomine Intermittent	PF	C10830 C10863		100	5	C
			Movapo Pen	TD	C10830 C10863		100	5	C
Atazanavir	Capsule 200 mg (as sulfate)	Oral	Atazanavir Mylan	AF	C4454 C4512		120	5	D
			Reyataz	BQ	C4454 C4512		120	5	D
	Capsule 300 mg (as sulfate)	Oral	Atazanavir Mylan	AF	C4454 C4512		60	5	D
			Reyataz	BQ	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	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Atazanavir with cobicistat	Tablet containing 300 mg atazanavir and 150 mg cobicistat	Oral	Evotaz	BQ	C4454 C4512		60	5	D
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Accord	OC	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D
			AZACITIDINE DR.REDDY'S	RI	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D
			Azacitidine Juno	JO	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D
			Azacitidine-Teva	TB	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D
			Azadine	RZ	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Celazadine	JU	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D
			Vidaza	CJ	C6132 C6143 C6144 C6177 C6186 C6199		See Note 1	See Note 2	D
Azithromycin	Tablet 600 mg (as dihydrate)	Oral	Zithromax	PF	C6356 C9604		16	5	PB
Baclofen	Intrathecal injection 10 mg in 5 mL	Injection	Bacthecal	DZ	C6911 C6925 C6939 C6940 C9488 C9489 C9524 C9637		10	0	PB
			Lioresal Intrathecal	NV	C6911 C6925 C6939 C6940 C9488 C9489 C9524 C9637		10	0	PB
			Sintetica Baclofen Intrathecal	BZ	C6911 C6925 C6939 C6940 C9488 C9489 C9524 C9637		10	0	PB

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Intrathecal injection 40 mg in 20 mL	Injection	Sintetica Baclofen Intrathecal	BZ	C7134 C7148 C7152 C7153 C9525 C9562 C9606 C9638		2	0	PB
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection	Fasenra Pen	AP	C9887 C10264 C10281 C10314	P9887	1	0	D
					C9887 C10264 C10281 C10314	P10281	1	2	D
					C9887 C10264 C10281 C10314	P10264 P10314	1	4	D
	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection	Fasenra	AP	C9887 C10264 C10281 C10314	P9887	1	0	D
					C9887 C10264 C10281 C10314	P10281	1	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C9887 C10264 C10281 C10314	P10264 P10314	1	4	D
Bictegravir with emtricitabine with tenofovir alafenamide	Tablet containing bictegravir 50 mg with emtricitabine 200 mg with tenofovir alafenamide 25 mg	Oral	Biktarvy	GI	C4470 C4522		60	5	D
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Bosentan APO	GX	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			BOSENTAN DR. REDDY'S	RI	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			Bosentan Mylan	AF	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Bosentan RBX	RA	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			Bosentan Sandoz	SZ	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			BOSLEER	RW	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			Tracleer	JC	C10228 C10238 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 125 mg (as monohydrate)	Oral	Bosentan APO	GX	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			BOSENTAN DR. REDDY'S	RI	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Bosentan GH	GQ	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			Bosentan Mylan	AF	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Bosentan RBX	RA	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			Bosentan Sandoz	SZ	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			BOSLEER	RW	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
			Tracleer	JC	C10228 C10722 C10724 C10725 C10728 C10795 C10924 C10945		See Note 1	See Note 2	D
Ciclosporin	Capsule 10 mg	Oral	Neoral 10	NV	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 25 mg	Oral	Cyclosporin Sandoz	SZ	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C
			Neoral 25	NV	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C
	Capsule 50 mg	Oral	Cyclosporin Sandoz	SZ	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C
			Neoral 50	NV	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 100 mg	Oral	Cyclosporin Sandoz	SZ	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C
			Neoral 100	NV	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		120	5	C
	Oral liquid 100 mg per mL, 50 mL	Oral	Neoral	NV	C6631 C6638 C6643 C6660 C6676 C9694 C9695 C9742 C9763 C9764		4	5	C
	Solution concentrate for I.V. infusion 50 mg in 1 mL	Injection	Sandimmun	NV	C6628 C9831		10	0	PB
Cinacalcet	Tablet 30 mg (as hydrochloride)	Oral	Pharmacor Cinacalcet	CR	C10063 C10067 C10073		56	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 60 mg (as hydrochloride)	Oral	Pharmacor Cinacalcet	CR	C10063 C10067 C10073		56	5	C
	Tablet 90 mg (as hydrochloride)	Oral	Pharmacor Cinacalcet	CR	C10063 C10067 C10073		56	5	C
Clozapine	Tablet 25 mg	Oral	Clopine 25	PF	C4998 C5015 C9490		200	0	D
			Clozaril 25	GO	C4998 C5015 C9490		200	0	D
	Tablet 50 mg	Oral	Clopine 50	PF	C4998 C5015 C9490		200	0	D
	Tablet 100 mg	Oral	Clopine 100	PF	C4998 C5015 C9490		200	0	D
			Clozaril 100	GO	C4998 C5015 C9490		200	0	D
	Tablet 200 mg	Oral	Clopine 200	PF	C4998 C5015 C9490		200	0	D
	Oral liquid 50 mg per mL, 100 mL	Oral	Clopine Suspension	PF	C4998 C5015 C9490		1	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Versacloz	PF	C4998 C5015 C9490		1	0	D
Darbepoetin Alfa	Injection 10 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 20 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 20 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	C6294 C9688		8	5	D
	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 40 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 40 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	C6294 C9688		8	5	D
	Injection 50 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 60 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 60 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	C6294 C9688		8	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 80 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 80 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	C6294 C9688		8	5	D
	Injection 100 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 100 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	C6294 C9688		8	5	D
	Injection 150 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	C6294 C9688		8	5	D
	Injection 150 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	C6294 C9688		8	5	D
Darunavir	Tablet 600 mg (as ethanolate)	Oral	Prezista	JC	C5094		120	5	D
	Tablet 800mg (as ethanolate)	Oral	Prezista	JC	C4313		60	5	D
Darunavir with cobicistat	Tablet containing darunavir 800mg with cobicistat 150 mg	Oral	Prezcobix	JC	C6377 C6413 C6428		60	5	D
Darunavir with cobicistat, emtricitabine and tenofovir alafenamide	Tablet containing darunavir 800 mg with cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg	Oral	Symtuza	JC	C10317 C10324		60	5	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Deferasirox	Tablet 90 mg	Oral	Jadenu	NM	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2	D
					C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5	D
	Tablet 180 mg	Oral	Jadenu	NM	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2	D
					C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 360 mg	Oral	Jadenu	NM	C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7385 P8326 P8328 P8329 P9222 P9258 P9302	180	2	D
					C7374 C7375 C7385 C8326 C8328 C8329 C9222 C9258 C9302	P7374 P7375	180	5	D
Deferiprone	Tablet 500 mg	Oral	Ferriprox	EU	C6403 C6448 C9228 C9286		300	5	D
	Tablet 1000 mg	Oral	Ferriprox	EU	C6403 C6448 C9590 C9623		300	5	D
	Oral solution 100 mg per mL, 250 mL	Oral	Ferriprox	EU	C6403 C6448 C9228 C9286		5	5	D
Desferrioxamine	Powder for injection containing desferrioxamine mesilate 500 mg	Injection	DBL Desferrioxamine Mesilate	PF	C6394 C9696		400	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for injection containing desferrioxamine mesilate 2 g	Injection	DBL Desferrioxamine Mesilate	PF	C6394 C9696		60	5	D
Dolutegravir	Tablet 50mg (as sodium)	Oral	Tivicay	VI	C4454 C4512		60	5	D
Dolutegravir with abacavir and lamivudine	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	Oral	Triumeq	VI	C9981 C10116		60	5	D
Dolutegravir with lamivudine	Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg	Oral	Dovato	VI	C9909 C9934 C9987		60	5	D
Dolutegravir with rilpivirine	Tablet containing dolutegravir 50 mg (as sodium) with rilpivirine 25 mg (as hydrochloride)	Oral	Juluca	VI	C8214 C8226		60	5	D
Dornase Alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation	Pulmozyme	RO	C5634 C5635 C5740 C9591 C9592 C9624		60	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Doxorubicin - Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	JC	C6234 C6274 C9223 C9287		4	5	D
			Liposomal Doxorubicin SUN	RA	C6234 C6274 C9223 C9287		4	5	D
Eculizumab	Solution concentrate for I.V. infusion 300 mg in 30 mL	Injection	Soliris	XI	C6626 C6637 C6642 C6668 C6686 C6687 C6688	P6626	1	0	D
					C6626 C6637 C6642 C6668 C6686 C6687 C6688	P6642	1	4	D
					C6626 C6637 C6642 C6668 C6686 C6687 C6688	P6668 P6686 P6687 P6688	1	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C6626 C6637 C6642 C6668 C6686 C6687 C6688	P6637	1	6	D
Efavirenz	Tablet 200 mg	Oral	Stocrin	MK	C4454 C4512		180	5	D
	Tablet 600 mg	Oral	Stocrin	MK	C4454 C4512		60	5	D
	Oral solution 30 mg per mL, 180 mL	Oral	Stocrin	MK	C4454 C4512		7	5	D
Eltrombopag	Tablet 25 mg (as olamine)	Oral	Revolade	NV	C6724 C6725 C6738 C6739 C6790		See Note 1	See Note 2	D
	Tablet 50 mg (as olamine)	Oral	Revolade	NV	C6724 C6725 C6738 C6739 C6790		See Note 1	See Note 2	D
Emtricitabine with rilpivirine with tenofovir alafenamide	Tablet containing emtricitabine 200 mg with rilpivirine 25 mg with tenofovir alafenamide 25 mg	Oral	Odefsey	GI	C4470 C4522		60	5	D
Emtricitabine with tenofovir alafenamide	Tablet containing emtricitabine 200 mg with tenofovir alafenamide 10 mg	Oral	Descovy	GI	C4454 C4512		60	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet containing emtricitabine 200 mg with tenofovir alafenamide 25 mg	Oral	Descovy	GI	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	C5014		2	5	D
Entecavir	Tablet 0.5 mg (as monohydrate)	Oral	Baraclude	BQ	C4993 C5036		60	5	D
			ENTAC	LR	C4993 C5036		60	5	D
			Entecavir Amneal	EA	C4993 C5036		60	5	D
			ENTECAVIR APO	GX	C4993 C5036		60	5	D
			Entecavir APOTEX	TX	C4993 C5036		60	5	D
			Entecavir GH	GQ	C4993 C5036		60	5	D
			Entecavir Mylan	AF	C4993 C5036		60	5	D

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			ENTECAVIR RBX	RA	C4993 C5036		60	5	D
			Entecavir Sandoz	SZ	C4993 C5036		60	5	D
			ENTECLUDE	RW	C4993 C5036		60	5	D
	Tablet 1 mg (as monohydrate)	Oral	Baraclude	BQ	C5037 C5044		60	5	D
			ENTAC	LR	C5037 C5044		60	5	D
			Entecavir Amneal	EA	C5037 C5044		60	5	D
			ENTECAVIR APO	GX	C5037 C5044		60	5	D
			Entecavir APOTEX	TX	C5037 C5044		60	5	D
			Entecavir GH	GQ	C5037 C5044		60	5	D
			Entecavir Mylan	AF	C5037 C5044		60	5	D
			ENTECAVIR RBX	RA	C5037 C5044		60	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Entecavir Sandoz	SZ	C5037 C5044		60	5	D
			ENTECLUDE	RW	C5037 C5044		60	5	D
Epoetin Alfa	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 1000	JC	C6294 C9688		12	5	D
	Injection 2,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 2000	JC	C6294 C9688		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Eprex 3000	JC	C6294 C9688		12	5	D
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Eprex 4000	JC	C6294 C9688		12	5	D
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 5000	JC	C6294 C9688		12	5	D
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Eprex 6000	JC	C6294 C9688		12	5	D
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Eprex 8000	JC	C6294 C9688		12	5	D
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Eprex 10000	JC	C6294 C9688		12	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 20,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 20,000	JC	C6294 C9688		12	5	D
	Injection 40,000 units in 1 mL pre-filled syringe	Injection	Eprex 40,000	JC	C6294 C9688		2	5	D
Epoetin Beta	Injection 2,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	C6294 C9688		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	C6294 C9688		12	5	D
	Injection 4,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	C6294 C9688		12	5	D
	Injection 5,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	C6294 C9688		12	5	D
	Injection 6,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	C6294 C9688		12	5	D
	Injection 10,000 units in 0.6 mL pre-filled syringe	Injection	NeoRecormon	RO	C6294 C9688		12	5	D
Epoetin lambda	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
	Injection 2,000 units in 1 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Novicrit	SZ	C6294 C9688		12	5	D
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection	EPOPROS TENOL SUN	RA	C10228 C10240 C10241		See Note 1	See Note 2	D
			Veletri	JC	C10228 C10240 C10241		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection	Flolan	GK	C10228 C10240 C10241		See Note 1	See Note 2	D
	Powder for I.V. infusion 1.5 mg (as sodium)	Injection	EPOPROSTENOL SUN	RA	C10228 C10240 C10241		See Note 1	See Note 2	D
			Veletri	JC	C10228 C10240 C10241		See Note 1	See Note 2	D
	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection	Flolan	GK	C10228 C10240 C10241		See Note 1	See Note 2	D
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	C9384 C9417 C10548 C10578 C10579 C10599		See Note 1	See Note 2	C
	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	C9384 C9417 C10548 C10578 C10579 C10599		See Note 1	See Note 2	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	C9384 C9417 C10548 C10578 C10579 C10599		See Note 1	See Note 2	C
Etravirine	Tablet 200 mg	Oral	Intelence	JC	C5014		120	5	D
Everolimus	Tablet 0.25 mg	Oral	Certican	NV	C5554 C5795 C9691 C9693		120	5	C
	Tablet 0.5 mg	Oral	Certican	NV	C5554 C5795 C9691 C9693		120	5	C
	Tablet 0.75 mg	Oral	Certican	NV	C5554 C5795 C9691 C9693		240	5	C
	Tablet 1 mg	Oral	Certican	NV	C5554 C5795 C9691 C9693		240	5	C

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	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	PF	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D
	Injection 300 micrograms in 0.5 mL single-use pre-filled syringe	Injection	Neupogen	AN	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Nivestim	PF	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D
			Zarzio	SZ	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 300 micrograms in 1 mL	Injection	Neupogen	AN	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D
	Injection 480 micrograms in 0.5 mL single-use pre-filled syringe	Injection	Neupogen	AN	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Nivestim	PF	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D
			Zarzio	SZ	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	AN	C6621 C6640 C6653 C6654 C6655 C6679 C6680 C7822 C7843 C8667 C8668 C8669 C8670 C8671 C8672 C8673 C8674 C8696		20	11	D
Fosamprenavir	Tablet 700 mg (as calcium)	Oral	Telzir	VI	C4454 C4512		120	5	D
Ganciclovir	Powder for I.V. infusion 500 mg (as sodium)	Injection	Cymevene	PB	C4972 C4999 C5000 C9404 C9526		10	1	D
			GANCICLOVIR SXP	HN	C4972 C4999 C5000 C9404 C9526		10	1	D
Glecaprevir with pibrentasvir	Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir	Oral	Maviret	VE	C7593 C7615 C10268	P7593	84	1	
					C7593 C7615 C10268	P7615	84	2	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C7593 C7615 C10268	P10268	84	3	
Grazoprevir with elbasvir	Tablet containing grazoprevir 100 mg with elbasvir 50 mg	Oral	Zepatier	MK	C5969 C6625	P5969	28	2	
					C5969 C6625	P6625	28	3	
Ibandronic acid	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	Injection	Bondronat	IX	C5291 C9333		1	11	PB
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation	Ventavis	BN	C10228 C10229 C10284		See Note 1	See Note 2	D
Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	PF	C4524 C7777 C8296 C8644 C8645 C8646 C8715 C8743 C8744 C8745 C8755 C8800 C8801 C8844 C8881 C8883 C8885 C8886 C8940 C8941 C8962 C8983		See Note 1	See Note 2	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
				C9065 C9067 C9068 C9110 C9111 C9169 C9188 C9191 C9400 C9401 C9402 C9472 C9481 C9487 C9558 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9675 C9676 C9677 C9719 C9721 C9731 C9732 C9733 C9751 C9752 C9754 C9756 C9759 C9775 C9776 C9778 C9779 C9781 C9783 C9785 C9787 C9788 C9799				

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C9800 C9803 C9806 C9877 C9900 C9975 C9994				
			Remicade	JC	C4524 C7777 C8296 C8644 C8645 C8646 C8715 C8743 C8744 C8745 C8800 C8801 C8881 C8883 C8885 C8886 C8941 C8962 C8983 C9065 C9067 C9068 C9110 C9111 C9169 C9191 C9400 C9401 C9402 C9487 C9558 C9559 C9587 C9632 C9669 C9675 C9676 C9677		See Note 1	See Note 2	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C9719 C9721 C9751 C9752 C9754 C9756 C9759 C9776 C9778 C9779 C9781 C9783 C9788 C9799 C9800 C9803 C9877 C9900 C9994				
			Renflexis	MK	C4524 C7777 C8296 C8644 C8645 C8646 C8715 C8743 C8744 C8745 C8755 C8800 C8801 C8844 C8881 C8883 C8885 C8886 C8940 C8941 C8962 C8983 C9065 C9067 C9068 C9110		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
				C9111 C9169 C9188 C9191 C9400 C9401 C9402 C9472 C9481 C9487 C9558 C9559 C9584 C9587 C9602 C9621 C9632 C9668 C9669 C9675 C9676 C9677 C9719 C9721 C9731 C9732 C9733 C9751 C9752 C9754 C9756 C9759 C9775 C9776 C9778 C9779 C9781 C9783 C9785 C9787 C9788 C9799 C9800 C9803 C9806 C9877				

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C9900 C9975 C9994				
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	C4993 C5036 C5042 C9259		30	5	C
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	C4993 C5036 C5042 C9259		30	5	C
Interferon Gamma-1b	Injection 2,000,000 I.U. in 0.5 mL	Injection	Imukin	EU	C6222 C9639		12	11	D
Ivacaftor	Sachet containing granules 50 mg	Oral	Kalydeco	VR	C9889 C9890		56	5	D
	Sachet containing granules 75 mg	Oral	Kalydeco	VR	C9889 C9890		56	5	D
	Tablet 150 mg	Oral	Kalydeco	VR	C9889 C9890		56	5	D
Lamivudine	Tablet 100 mg	Oral	Zeffix	RW	C4993 C5036		56	5	D
			Zetlam	AF	C4993 C5036		56	5	D
	Tablet 150 mg	Oral	3TC	VI	C4454 C4512		120	5	D
			Lamivudine Alphapharm	AF	C4454 C4512		120	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 300 mg	Oral	3TC	VI	C4454 C4512		60	5	D
			Lamivudine Alphapharm	AF	C4454 C4512		60	5	D
	Oral solution 10 mg per mL, 240 mL	Oral	3TC	VI	C4454 C4512		8	5	D
Lamivudine with Zidovudine	Tablet 150 mg-300 mg	Oral	Combivir	VI	C4454 C4512		120	5	D
			Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	AF	C4454 C4512		120	5	D
Lanreotide	Injection 60 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	C4575 C7025 C7509 C7532 C9260 C9261		2	5	D
	Injection 90 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	C4575 C7025 C7509 C7532 C9260 C9261		2	5	D
	Injection 120 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	C4575 C7025 C7509 C7532 C9260 C9261 C10061		2	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10075 C10077				
	Powder for suspension for injection 30 mg (as acetate) with diluent	Injection	Somatuline LA	IS	C7042 C9225		2	11	D
Lanthanum	Tablet, chewable, 500 mg (as carbonate hydrate)	Oral	Fosrenol	TK	C5530 C9762		180	5	C
	Tablet, chewable, 750 mg (as carbonate hydrate)	Oral	Fosrenol	TK	C5530 C9762		180	5	C
	Tablet, chewable, 1000 mg (as carbonate hydrate)	Oral	Fosrenol	TK	C5530 C9762		180	5	C
Ledipasvir with sofosbuvir	Tablet containing 90 mg ledipasvir with 400 mg sofosbuvir	Oral	Harvoni	GI	C5944 C5969 C5972	P5944	28	1	
					C5944 C5969 C5972	P5969	28	2	
					C5944 C5969 C5972	P5972	28	5	
Lenalidomide	Capsule 5 mg	Oral	Revlimid	CJ	C4282 C4287 C10334		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10335 C10349 C10350 C10373 C10427 C10428 C10429 C10452 C10453				
	Capsule 10 mg	Oral	Revlimid	CJ	C4282 C4287 C10334 C10335 C10349 C10350 C10373 C10427 C10428 C10429 C10452 C10453		See Note 1	See Note 2	D
	Capsule 15 mg	Oral	Revlimid	CJ	C10334 C10335 C10349		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10350 C10373 C10427 C10428 C10429 C10452 C10453				
	Capsule 25 mg	Oral	Revlimid	CJ	C10349 C10350 C10373 C10427 C10428 C10429 C10452 C10453		See Note 1	See Note 2	D
Levodopa with carbidopa	Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL	Intra-intestinal	Duodopa	VE	C10138 C10161 C10363 C10375	P10138 P10161	28	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10138 C10161 C10363 C10375	P10363 P10375	56	5	C
Lipegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Lonquex	TB	C7822 C7843 C9224 C9322		1	11	D
Lopinavir with Ritonavir	Tablet 100 mg-25 mg	Oral	Kaletra	VE	C4454 C4512		120	5	D
	Tablet 200 mg-50 mg	Oral	Kaletra	VE	C4454 C4512		240	5	D
	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	Oral	Kaletra	VE	C4454 C4512		10	5	D
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral	Orkambi	VR	C10005 C10007		56	5	D
	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral	Orkambi	VR	C10005 C10007		56	5	D
	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral	Orkambi	VR	C9891 C9920		112	5	D
	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral	Orkambi	VR	C9857 C9943		112	5	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Macitentan	Tablet 10 mg	Oral	Opsumit	JC	C10228 C10236 C10285 C10728 C10845 C10846 C10850 C10869		30	5	D
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth	bronchitol	XA	C7362 C7367 C9527 C9593		4	5	D
Maraviroc	Tablet 150 mg	Oral	Celsentri	VI	C5008		120	5	D
	Tablet 300 mg	Oral	Celsentri	VI	C5008		120	5	D
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen	Injection	Nucala	GK	C9885 C10221 C10222 C10280 C10483 C10484	P9885	1	0	D
					C9885 C10221 C10222 C10280 C10483	P10280 P10483 P10484	1	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10484				
					C9885 C10221 C10222 C10280 C10483 C10484	P10221 P10222	1	7	D
	Powder for injection 100 mg	Injection	Nucala	GK	C9885 C10221 C10222 C10280	P9885	1	0	D
					C9885 C10221 C10222 C10280	P10280	1	5	D
					C9885 C10221 C10222 C10280	P10221 P10222	1	7	D
Methoxsalen	Solution for blood fraction 20 microgram per mL, 10 mL	Extracorporeal Circulation	Uvadex	TQ	C10971 C10985 C10988 C10989	P10988 P10989	1	5	D
					C10971 C10985	P10971 P10985	2	6	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10988 C10989				
Methoxy polyethylene glycol-epoetin beta	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
	Injection 50 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
	Injection 75 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
	Injection 100 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
	Injection 120 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
	Injection 200 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
	Injection 360 micrograms in 0.6 mL pre-filled syringe	Injection	Mircera	RO	C6294 C9688		2	5	D
Midostaurin	Capsule 25 mg	Oral	Rydapt	NV	C8138 C8177 C8193 C8218	P8193	56	2	D
					C8138 C8177 C8193 C8218	P8218	112	1	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C8138 C8177 C8193 C8218	P8138 P8177	112	2	D
Mycophenolic Acid	Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid	Oral	Myfortic	NV	C4084 C4095 C9692 C9809		240	5	C
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	Myfortic	NV	C4084 C4095 C9692 C9809		240	5	C
	Capsule containing mycophenolate mofetil 250 mg	Oral	APO-Mycophenolate	TX	C5600 C5653 C9689 C9690		600	5	C
			CellCept	RO	C5600 C5653 C9689 C9690		600	5	C
			Ceptolate	AF	C5600 C5653 C9689 C9690		600	5	C
			Mycophenolate Sandoz	SZ	C5600 C5653 C9689 C9690		600	5	C
			Pharmacor Mycophenolate 250	CR	C5600 C5653 C9689 C9690		600	5	C

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet containing mycophenolate mofetil 500 mg	Oral	APO-Mycophenolate	TX	C5554 C5795 C9691 C9693		300	5	C
			CellCept	RO	C5554 C5795 C9691 C9693		300	5	C
			Ceptolate	AF	C5554 C5795 C9691 C9693		300	5	C
			MycoCept	RF	C5554 C5795 C9691 C9693		300	5	C
			Mycophenolate AN	EA	C5554 C5795 C9691 C9693		300	5	C
			Mycophenolate APOTEX	GX	C5554 C5795 C9691 C9693		300	5	C
			Mycophenolate GH	GQ	C5554 C5795 C9691 C9693		300	5	C
			Mycophenolate Sandoz	SZ	C5554 C5795 C9691 C9693		300	5	C
			Pharmacor Mycophenolate 500	CR	C5554 C5795 C9691 C9693		300	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	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	C5554 C5795 C9691 C9693		2	5	C
Natalizumab	Solution concentrate for I.V. infusion 300 mg in 15 mL	Injection	Tysabri	BD	C9744 C9818		1	5	D
Nevirapine	Tablet 200 mg	Oral	Nevirapine Alphapharm	AF	C4454 C4512		120	5	D
	Tablet 400 mg (extended release)	Oral	Nevirapine XR APOTEX	TX	C4454 C4526		60	5	D
			Viramune XR	BY	C4454 C4526		60	5	D
	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	Oral	Viramune	BY	C4454 C4512		10	5	D
Nusinersen	Solution for injection 12 mg in 5 mL	Injection	Spinraza	BD	C7849 C10112		See Note 1	See Note 2	D
Ocrelizumab	Solution concentrate for I.V. infusion 300 mg in 10 mL	Injection	Ocrevus	RO	C7386 C7699 C9523 C9635		2	0	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Octreotide	Injection 50 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	HQ	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Octreotide MaxRx	GQ	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Octreotide (SUN)	RA	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Sandostatin 0.05	NV	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
	Injection 100 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	HQ	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Octreotide MaxRx	GQ	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Octreotide (SUN)	RA	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Sandostatin 0.1	NV	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
	Injection 500 micrograms (as acetate) in 1 mL	Injection	Octreotide GH	HQ	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Octreotide MaxRx	GQ	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Octreotide (SUN)	RA	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
			Sandostatin 0.5	NV	C6369 C6390 C8165 C9232 C9233 C9289		90	11	D
	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313		2	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313		2	5	D
	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	C5901 C5906 C8161 C8197 C8198 C8208 C9262 C9288 C9313 C10061 C10075 C10077		2	5	D
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Xolair	NV	C9855 C10219 C10223 C10226 C10265 C10279 C10299		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Xolair	NV	C7046 C7055 C9855 C10219 C10223 C10226 C10265 C10279 C10299		See Note 1	See Note 2	D
Pamidronic Acid	Concentrated injection containing pamidronate disodium 15 mg in 5 mL	Injection	Pamisol	PF	C4433 C9234		4	2	C
	Concentrated injection containing pamidronate disodium 30 mg in 10 mL	Injection	Pamisol	PF	C4433 C9234		2	2	C
	Concentrated injection containing pamidronate disodium 60 mg in 10 mL	Injection	Pamisol	PF	C4433 C9234		1	2	C
	Concentrated injection containing pamidronate disodium 90 mg in 10 mL	Injection	Pamisol	PF	C4433 C5218 C5291 C9234 C9315 C9335		1	11	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Pasireotide	Injection (modified release) 20 mg (as embonate), vial and diluent syringe	Injection	Signifor LAR	RJ	C9088 C9089		See Note 1	See Note 2	D
	Injection (modified release) 40 mg (as embonate), vial and diluent syringe	Injection	Signifor LAR	RJ	C9088 C9089		See Note 1	See Note 2	D
	Injection (modified release) 60 mg (as embonate), vial and diluent syringe	Injection	Signifor LAR	RJ	C9088 C9089		See Note 1	See Note 2	D
Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Fulphila	AF	C7822 C7843 C9235 C9303		1	11	D
			Neulasta	JU	C7822 C7843 C9235 C9303		1	11	D
			Pelgraz	OC	C7822 C7843 C9235 C9303		1	11	D
			Ristempa	JO	C7822 C7843 C9235 C9303		1	11	D
			Tezmota	JX	C7822 C7843 C9235 C9303		1	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Ziextenzo	SZ	C7822 C7843 C9235 C9303		1	11	D
Peginterferon alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	C5004 C9603		8	5	C
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	C5004 C9603		8	5	C
Pegvisomant	Injection set containing powder for injection 10 mg, 30 and diluent, 30	Injection	Somavert	PF	C7087 C9041		See Note 1	See Note 2	D
	Injection set containing powder for injection 15 mg, 30 and diluent, 30	Injection	Somavert	PF	C7087 C9041		See Note 1	See Note 2	D
	Injection set containing powder for injection 20 mg, 1 and diluent, 1	Injection	Somavert	PF	C9041		See Note 1	See Note 2	D
	Injection set containing powder for injection 20 mg, 30 and diluent, 30	Injection	Somavert	PF	C7087 C9041		See Note 1	See Note 2	D
Plerixafor	Injection 24 mg in 1.2 mL	Injection	Mozobil	GZ	C4549 C9329		1	1	D
Pomalidomide	Capsule 3 mg	Oral	Pomalyst	CJ	C7791 C7952		21	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 4 mg	Oral	Pomalyst	CJ	C7791 C7952		21	0	D
Raltegravir	Tablet 25 mg (as potassium)	Oral	Isentress	MK	C4274 C4275		360	5	D
	Tablet 100 mg (as potassium)	Oral	Isentress	MK	C4274 C4275		360	5	D
	Tablet 400 mg (as potassium)	Oral	Isentress	MK	C4454 C4512		120	5	D
	Tablet 600 mg (as potassium)	Oral	Isentress HD	MK	C4454 C4512		120	5	D
Ribavirin	Tablet 400 mg	Oral	Ibavyr	IX	C5957 C5958	P5957	28	2	
					C5957 C5958	P5958	28	5	
	Tablet 600 mg	Oral	Ibavyr	IX	C5957 C5958	P5957	28	2	
					C5957 C5958	P5958	28	5	
Rifabutin	Capsule 150 mg	Oral	Mycobutin	PF	C6350 C6356 C9560 C9622		120	5	D
Rilpivirine	Tablet 25 mg (as hydrochloride)	Oral	Edurant	JC	C4454 C4512		60	5	D
Riociguat	Tablet 500 micrograms	Oral	Adempas	BN	C6645 C6664 C7629 C10231 C10243 C10245		See note 1	See note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 1 mg	Oral	Adempas	BN	C6645 C6664 C7629 C10231 C10243 C10245		See note 1	See note 2	D
	Tablet 1.5 mg	Oral	Adempas	BN	C6645 C6664 C7629 C10231 C10243 C10245		See note 1	See note 2	D
	Tablet 2 mg	Oral	Adempas	BN	C6645 C6664 C7629 C10231 C10243 C10245		See note 1	See note 2	D
	Tablet 2.5 mg	Oral	Adempas	BN	C6645 C6664 C7629 C10231 C10243 C10245		See note 1	See note 2	D
Ritonavir	Tablet 100 mg	Oral	Norvir	VE	C4454 C4512		720	5	D
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Mabthera	RO	C7021 C7022 C9344 C9511		See Note 1	See Note 2	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Riximyo	SZ	C7021 C7022 C9336 C9344 C9511 C9539 C9640 C9641		See Note 1	See Note 2	PB
			Truxima	EW	C7021 C7022 C9336 C9344 C9511 C9539 C9640 C9641		See Note 1	See Note 2	PB
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	RO	C7021 C7022 C9340 C9344 C9448 C9449 C9450 C9511 C9512		See Note 1	See Note 2	PB
			Riximyo	SZ	C7021 C7022 C9336 C9340 C9344 C9446 C9448 C9449 C9450 C9511 C9512 C9539 C9611 C9640 C9641		See Note 1	See Note 2	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Truxima	EW	C7021 C7022 C9336 C9340 C9344 C9446 C9448 C9449 C9450 C9511 C9512 C9539 C9611 C9640 C9641		See Note 1	See Note 2	PB
Romiplostim	Powder for injection 375 micrograms	Injection	Nplate	AN	C6694 C6737 C6738 C6766 C6789		See Note 1	See Note 2	D
	Powder for injection 625 micrograms	Injection	Nplate	AN	C6694 C6737 C6738 C6766 C6789		See Note 1	See Note 2	D
Saquinavir	Tablet 500 mg (as mesilate)	Oral	Invirase	RO	C4454 C4512		240	5	D
Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral	Sevelamer Apotex	TX	C5530 C9762		360	5	C
			Sevelamer Lupin	GQ	C5530 C9762		360	5	C
	Tablet containing sevelamer hydrochloride 800 mg	Oral	Renagel	GZ	C5530 C9762		360	5	C

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Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Sildenafil	Tablet 20 mg (as citrate)	Oral	APO-Sildenafil PHT	TX	C10228 C10234 C10304 C10726 C10732 C10797 C10848 C10868		See Note 1	See Note 2	D
			Revatio	UJ	C10228 C10234 C10304 C10726 C10732 C10797 C10848 C10868		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			SILDATIO PHT	RW	C10228 C10234 C10304 C10726 C10732 C10797 C10848 C10868		See Note 1	See Note 2	D
			Sildenafil AN PHT 20	EA	C10228 C10234 C10304 C10726 C10732 C10797 C10848 C10868		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Sildenafil Sandoz PHT 20	SZ	C10228 C10234 C10304 C10726 C10732 C10797 C10848 C10868		See Note 1	See Note 2	D
Sirolimus	Tablet 0.5 mg	Oral	Rapamune	PF	C5795 C9914		200	5	C
	Tablet 1 mg	Oral	Rapamune	PF	C5795 C9914		200	5	C
	Tablet 2 mg	Oral	Rapamune	PF	C5795 C9914		200	5	C
	Oral solution 1 mg per mL, 60 mL	Oral	Rapamune	PF	C5795 C9914		2	5	C
Sofosbuvir with velpatasvir	Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir	Oral	Epclusa	GI	C5969		28	2	
Sofosbuvir with velpatasvir and voxilaprevir	Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir and 100 mg voxilaprevir	Oral	Vosevi	GI	C10248		28	2	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Sucroferric oxyhydroxide	Tablet, chewable, 2.5 g (equivalent to 500 mg iron)	Oral	Velphoro	VL	C5530 C9762		180	5	C
Tacrolimus	Capsule 0.5 mg	Oral	Pacrolim	AF	C5569 C9697		200	5	C
			Pharmacor Tacrolimus 0.5	CR	C5569 C9697		200	5	C
			Prograf	LL	C5569 C9697		200	5	C
			Tacrograf	RW	C5569 C9697		200	5	C
			TACROLIMUS APOTEX	TX	C5569 C9697		200	5	C
			Tacrolimus Sandoz	SZ	C5569 C9697		200	5	C
	Capsule 0.5 mg (once daily prolonged release)	Oral	ADVAGRAF XL	LQ	C5569 C9697		60	5	C
	Capsule 0.75 mg	Oral	Tacrolimus Sandoz	SZ	C5569 C9697		200	5	C
	Capsule 1 mg	Oral	Pacrolim	AF	C5569 C9697		200	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Pharmacor Tacrolimus 1	CR	C5569 C9697		200	5	C
			Prograf	LL	C5569 C9697		200	5	C
			Tacrograf	RW	C5569 C9697		200	5	C
			TACROLIMUS APOTEX	TX	C5569 C9697		200	5	C
			Tacrolimus Sandoz	SZ	C5569 C9697		200	5	C
	Capsule 1 mg (once daily prolonged release)	Oral	ADVAGRAF XL	LQ	C5569 C9697		120	5	C
	Capsule 2 mg	Oral	Tacrolimus Sandoz	SZ	C5569 C9697		200	5	C
	Capsule 3 mg (once daily prolonged release)	Oral	ADVAGRAF XL	LQ	C5569 C9697		100	3	C
	Capsule 5 mg	Oral	Pacrolim	AF	C5569 C9697		100	5	C
			Pharmacor Tacrolimus 5	CR	C5569 C9697		100	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Prograf	LL	C5569 C9697		100	5	C
			Tacrograf	RW	C5569 C9697		100	5	C
			TACROLIMUS APOTEX	TX	C5569 C9697		100	5	C
			Tacrolimus Sandoz	SZ	C5569 C9697		100	5	C
	Capsule 5 mg (once daily prolonged release)	Oral	ADVAGRAF XL	LQ	C5569 C9697		60	5	C
Tadalafil	Tablet 20 mg	Oral	Adcirca	LY	C10228 C10234 C10304 C10726 C10731 C10732 C10733 C10799		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Tadalca	CR	C10228 C10234 C10304 C10726 C10731 C10732 C10733 C10799		See Note 1	See Note 2	D
Teduglutide	Powder for injection 5 mg with diluent	Injection	Revestive	TK	C9515 C9569 C9687 C9740 C9793 C9829		See Note 1	See Note 2	D
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg	Oral	Tenofovir APOTEX	TX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D
			Viread	GI	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Tenofovir APOTEX	TX	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D
			Viread	GI	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D
	Tablet containing tenofovir disoproxil maleate 300 mg	Oral	Tenofovir Disoproxil Mylan	AF	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D
					C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D
	Tablet containing tenofovir disoproxil phosphate 291 mg	Oral	Tenofovir GH	GQ	C6980 C6982 C6983 C6984 C6992 C6998 C10362	P10362	60	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C6980 C6982 C6983 C6984 C6992 C6998 C10362	P6980 P6982 P6983 P6984 P6992 P6998	60	5	D
Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat	Tablet containing tenofovir alafenamide 10 mg with emtricitabine 200 mg, elvitegravir 150 mg and cobicistat 150 mg	Oral	Genvoya	GI	C4470 C4522		60	5	D
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	Tenofovir/Emtricitabine 300/200 APOTEX	TX	C6985 C6986		60	5	C
	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	Oral	Tenofovir Disoproxil Emtricitabine Mylan 300/200	AF	C6985 C6986		60	5	C
	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	GQ	C6985 C6986		60	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	Oral	Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600	AF	C4470 C4522		60	5	D
Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral	Symdeko	VR	C9880 C9961 C10064 C10069		See Note 1	See Note 2	D
Thalidomide	Capsule 50 mg	Oral	Thalomid	CJ	C5914 C9290		112	0	D
	Capsule 100 mg	Oral	Thalomid	CJ	C5914 C9290		56	0	D
Tipranavir	Capsule 250 mg	Oral	Aptivus	BY	C5764		240	5	D

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Actemra	RO	C8627 C8635 C8636 C8637 C8638 C8709 C9380 C9384 C9386 C9407 C9417 C9494 C9495 C9496 C10532 C10535 C10536 C10541 C10542 C10545 C10567 C10570 C10571 C10616		See Note 1	See Note 2	PB
	Concentrate for injection 200 mg in 10 mL	Injection	Actemra	RO	C8627 C8635 C8636 C8637 C8638 C8709 C9380 C9384 C9386 C9407 C9417 C9494		See Note 1	See Note 2	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C9495 C9496 C10532 C10535 C10536 C10541 C10542 C10545 C10567 C10570 C10571 C10616				
	Concentrate for injection 400 mg in 20 mL	Injection	Actemra	RO	C8627 C8635 C8636 C8637 C8638 C8709 C9380 C9384 C9386 C9407 C9417 C9494 C9495 C9496 C10532 C10535 C10536 C10541 C10542		See Note 1	See Note 2	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
					C10545 C10567 C10570 C10571 C10616				
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection	Stelara	JC	C9655 C9656 C9710		See Note 1	See Note 2	PB
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	APO-Valaciclovir	TX	C5975 C9267		500	2	C
			Valaciclovir APOTEX	GX	C5975 C9267		500	2	C
			Valaciclovir RBX	RA	C5975 C9267		500	2	C
			Valtrex	RW	C5975 C9267		500	2	C
Valganciclovir	Tablet 450 mg (as hydrochloride)	Oral	Valcyte	RO	C4980 C4989 C9316		120	5	D
			Valganciclovir Mylan	AF	C4980 C4989 C9316		120	5	D
			Valganciclovir Sandoz	SZ	C4980 C4989 C9316		120	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	Oral	Valcyte	RO	C4980 C4989 C9316		11	5	D
Vedolizumab	Powder for injection 300 mg	Injection	Entyvio	TK	C9682 C9683 C9708 C9738 C9739 C9771 C9792 C9796 C9815 C9825		See Note 1	See Note 2	D
Zidovudine	Capsule 100 mg	Oral	Retrovir	VI	C4454 C4512		400	5	D
	Capsule 250 mg	Oral	Retrovir	VI	C4454 C4512		240	5	D
	Syrup 10 mg per mL, 200 mL	Oral	Retrovir	VI	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	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	PB
			DBL Zoledronic Acid	PF	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			DEZTRON	DZ	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	PB
			Zometa	NV	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	PB
	Solution for I.V. infusion 4 mg (as monohydrate) in 100 mL	Injection	DBL Zoledronic Acid	PF	C5605 C5703 C5704 C5735 C9268 C9304 C9317 C9328		1	11	PB

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
AP	AstraZeneca Pty Ltd	54 009 682 311
BD	Biogen 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
BY	Boehringer Ingelheim Pty Ltd	52 000 452 308
BZ	Boucher & Muir Pty Ltd	58 000 140 474
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	Amneal Pharmaceuticals Pty Ltd	11 163 167 851
EU	Chiesi Australia Pty Ltd	72 145 180 865
EW	Celltrion Healthcare Australia Pty Ltd	66 625 407 105
FK	A. Menarini Australia Pty Limited	62 116 935 758
GI	Gilead Sciences Pty Limited	71 072 611 708
GK	GlaxoSmithKline Australia Pty Ltd	47 100 162 481
GO	Mylan Health Pty Ltd	29 601 608 771
GQ	Generic Health Pty Ltd	93 110 617 859
GX	Apotex Pty Ltd	52 096 916 148
GZ	sanofi-aventis Australia Pty Ltd	31 008 558 807
HN	Horizon Hospital Healthcare Pty Ltd	60 148 910 883
HQ	Generic Health Pty Ltd	93 110 617 859
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
JO	Juno Pharmaceuticals Pty Ltd	55 156 303 650
JU	Juno Pharmaceuticals Pty Ltd	55 156 303 650
JX	Juno Pharmaceuticals Pty Ltd	55 156 303 650
LL	Astellas Pharma Australia Pty Ltd	81 147 915 482
LQ	Astellas Pharma Australia Pty Ltd	81 147 915 482
LR	Cipla Australia Pty Ltd	46 132 155 063
LY	Eli Lilly Australia Pty Ltd	39 000 233 992
MK	Merck Sharp & Dohme (Australia) Pty Ltd	14 000 173 508
NM	Novartis Pharmaceuticals Australia Pty Limited	18 004 244 160
NV	Novartis Pharmaceuticals Australia Pty Limited	18 004 244 160
OC	Accord Healthcare Pty Ltd	49 110 502 513
PB	Pharmaco (Australia) Limited	89 113 383 501
PF	Pfizer Australia Pty Ltd	50 008 422 348
RA	Sun Pharma ANZ Pty Ltd	17 110 871 826
RF	Arrow Pharma Pty Ltd	35 605 909 920
RI	Dr Reddy's Laboratories (Australia) Pty Ltd	16 120 092 408

Code	Responsible Person	Australian Business Number
RJ	Recordati Rare Diseases Australia Pty. Ltd	26 627 263 094
RO	Roche Products Pty Ltd	70 000 132 865
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
TQ	Terumo BCT Australia Pty Limited	87 130 046 865
TX	Apotex Pty Ltd	52 096 916 148
UJ	Upjohn Australia Pty Ltd	50 629 389 911
VE	AbbVie Pty Ltd	48 156 384 262
VI	ViiV Healthcare Pty Ltd	46 138 687 448
VL	Vifor Pharma Pty Limited	87 086 114 043
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

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4495		HIV infection Initial Patient must be antiretroviral treatment naïve; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Authority Required procedures - Streamlined Authority Code 4495
Abatacept	C8627		Severe active rheumatoid arthritis Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C8638		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C8655		Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8688		Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8748		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as:	Compliance with Written 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). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C8759		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance	Compliance with Written Authority Required procedures

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
Adalimumab	C9384		Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C9417		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR	Compliance with 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 for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
	C10582		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10583		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C10600		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10619		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. At the time of authority application, medical practitioners must request the appropriate number of injections 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. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
Adefovir	C4490		Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 4490

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4510		Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4510
Alemtuzumab	C6847	P6847	Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6847
	C7714	P7714	Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 7714
	C9589	P9589	Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 9589

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	
	C9636	P9636	Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9636
Ambrisentan	C10228		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C10236		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10285		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	

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Anakinra	C5450		Moderate to severe cryopyrin associated periodic syndromes (CAPS) Must be treated by a rheumatologist or in consultation with a rheumatologist; OR Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 5450
Apomorphine	C4833		Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 4833
	C9561		Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9561
	C10830		Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 10830
	C10863		Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND The treatment must be commenced in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 10863
Atazanavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Atazanavir with cobicistat	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4454

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4512		HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Azacitidine	C6132		Chronic Myelomonocytic Leukaemia Initial treatment The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and (d) a copy of the full blood examination report; and (e) a signed patient acknowledgement. No more than 3 cycles will be authorised.	Compliance with Written Authority Required procedures
	C6143		Acute Myeloid Leukaemia Initial treatment The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification. The first authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and (d) a copy of the full blood examination report; and (e) a signed patient acknowledgement. No more than 3 cycles will be authorised.	Compliance with Written Authority Required procedures
	C6144		Chronic Myelomonocytic Leukaemia Continuing treatment The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Up to 6 cycles will be authorised.	
	C6177		Myelodysplastic syndrome Initial treatment The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations: a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias. Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations: a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias. 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and (d) a copy of the full blood examination report; and (e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and (f) a signed patient acknowledgment form. No more than 3 cycles will be authorised.	
	C6186		Acute Myeloid Leukaemia Continuing treatment The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
	C6199		Myelodysplastic syndrome Continuing treatment The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Applications for continuing therapy may be made by telephone. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
Azithromycin	C6356		Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 6356
	C9604		Mycobacterium avium complex infection The treatment must be for prophylaxis; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Authority Code 9604
Baclofen	C6911		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 6911
	C6925		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 6925
	C6939		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 6939
	C6940		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 6940
	C7134		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 7134
	C7148		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 7148
	C7152		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 7152
	C7153		Severe chronic spasticity	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	Required procedures - Streamlined Authority Code 7153
	C9488		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 9488
	C9489		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Compliance with Authority Required procedures - Streamlined Authority Code 9489
	C9524		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9524
	C9525		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 9525
	C9562		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin.	Compliance with Authority Required procedures - Streamlined Authority Code 9562
	C9606		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9606
	C9637		Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis.	Compliance with Authority Required procedures - Streamlined Authority Code 9637
	C9638		Severe chronic spasticity	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	Required procedures - Streamlined Authority Code 9638
Benralizumab	C9887	P9887	Uncontrolled severe eosinophilic asthma Balance of supply Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.	Compliance with Authority Required procedures
	C10264	P10264	Uncontrolled severe eosinophilic asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND	Compliance with Written 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 and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following: (i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and (iii) eosinophil count and date; and (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy). An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine. At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Product Information). A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator.	
	C10281	P10281	Uncontrolled severe eosinophilic asthma Continuing treatment Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 12 years or older. An adequate response to this biological medicine is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5. All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made at around 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug. Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			response to treatment. A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS subsidised treatment with this biological medicine for severe asthma within the current treatment cycle. At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes: (i) details of maintenance oral corticosteroid dose; or (ii) a completed Asthma Control Questionnaire (ACQ-5) score.	
	C10314	P10314	Uncontrolled severe eosinophilic asthma Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND Patient must have a duration of asthma of at least 1 year; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be	

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			submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator. At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following: (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the eosinophil count and date; and (iv) Asthma Control Questionnaire (ACQ-5) score.	
Bictegravir with emtricitabine with tenofovir alafenamide	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522

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Bosentan	C10228		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10238		Pulmonary arterial hypertension (PAH) Cessation of treatment (all patients) Patient must be receiving PBS-subsidised treatment with this PAH agent; AND The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.	Compliance with Authority Required procedures
	C10722		Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	
	C10724		Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition; AND The treatment must be in combination with the PBS-subsidised PDE-5i for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	
	C10725		Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:	Compliance with Written 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). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10728		Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil.	Compliance with 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 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.	
	C10795		Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	
	C10924		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	Compliance with Authority Required procedures
	C10945		Pulmonary arterial hypertension (PAH)	Compliance with Written Authority

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 with expertise in the management of PAH; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) 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). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT;	Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats. Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.	
Ciclosporin	C6628		Management of transplant rejection The treatment must be used by organ or tissue transplant recipients.	Compliance with Authority Required procedures - Streamlined Authority Code 6628
	C6631		Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; OR Patient must be intolerant to treatment with steroids and cytostatic drugs; OR The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment. Must be treated by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6631
	C6638		Severe active rheumatoid arthritis Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR	Compliance with Authority Required procedures - Streamlined Authority Code 6638

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist.	
	C6643		Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 6643
	C6660		Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; OR Must be treated by a clinical immunologist. The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies.	Compliance with Authority Required procedures - Streamlined Authority Code 6660
	C6676		Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6676
	C9694		Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; OR Patient must be intolerant to treatment with steroids and cytostatic drugs; OR The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment. Must be treated by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9694
	C9695		Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; OR	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a clinical immunologists. The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies.	Authority Code 9695
	C9742		Severe active rheumatoid arthritis Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate). Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9742
	C9763		Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9763
	C9764		Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9764
	C9831		Management of transplant rejection The treatment must be used by organ or tissue transplant recipients.	Compliance with Authority Required procedures - Streamlined Authority Code 9831
Cinacalcet	C10063		Secondary hyperparathyroidism Continuing treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10063

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	
	C10067		Secondary hyperparathyroidism Continuing treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration. During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	Compliance with Authority Required procedures - Streamlined Authority Code 10067
	C10073		Secondary hyperparathyroidism Initial treatment Must be treated by a nephrologist. Patient must have chronic kidney disease; AND Patient must be on dialysis; AND Patient must have failed to respond to conventional therapy; AND Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L. During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.	Compliance with Authority Required procedures
Clozapine	C4998		Schizophrenia Continuing treatment	Compliance with Authority Required procedures -

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a psychiatrist; OR Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist. Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND Patient must have completed at least 18 weeks therapy; AND Patient must be on a clozapine dosage considered stable by a treating psychiatrist; AND The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Streamlined Authority Code 4998
	C5015		Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 5015
	C9490		Schizophrenia Initial treatment Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient. Patient must be non-responsive to other neuroleptic agents; OR Patient must be intolerant of other neuroleptic agents. Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction. The name of the consulting psychiatrist should be included in the patient's medical records. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.	Compliance with Authority Required procedures - Streamlined Authority Code 9490

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Darbepoetin Alfa	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Darunavir	C4313		Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND The treatment must be co-administered with 100 mg ritonavir, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, AND Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 4313
	C5094		Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND The treatment must be co-administered with 100 mg ritonavir twice daily, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 5094

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

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	C10324		HIV infection Initial treatment Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner. Patient must be antiretroviral treatment naive; OR Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND The treatment must not be in combination with ritonavir. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 10324
Deferasirox	C7374	P7374	Chronic iron overload Initial treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia.	Compliance with Authority Required procedures
	C7375	P7375	Chronic iron overload Initial treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis.	Compliance with Authority Required procedures
	C7385	P7385	Chronic iron overload Initial treatment Patient must be red blood cell transfusion dependent; AND Patient must have a serum ferritin level of greater than 1000 microgram/L; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have a median life expectancy exceeding five years.	Compliance with Authority Required procedures
	C8326	P8326	Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoieisis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8326
	C8328	P8328	Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Authority Code 8328
	C8329	P8329	Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8329
	C9222	P9222	Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9222
	C9258	P9258	Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoieisis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9258
	C9302	P9302	Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9302
Deferiprone	C6403		Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 6403
	C6448		Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6448

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C9228		Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 9228
	C9286		Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9286
	C9590		Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective.	Compliance with Authority Required procedures - Streamlined Authority Code 9590
	C9623		Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9623
Desferrioxamine	C6394		Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined Authority Code 6394
	C9696		Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined Authority Code 9696
Dolutegravir	C4454		HIV infection Continuing Patient must have previously received PBS subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Dolutegravir with abacavir and lamivudine	C9981		HIV infection Initial treatment Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 9981
	C10116		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 10116
Dolutegravir with lamivudine	C9909		HIV infection Grandfathered treatment Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019; AND Patient must have been antiretroviral treatment naive prior to initiating this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9909
	C9934		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 9934
	C9987		HIV infection Initial treatment Patient must be antiretroviral treatment naive; AND Patient must not have suspected resistance to either antiretroviral component.	Compliance with Authority Required procedures - Streamlined Authority Code 9987
Dolutegravir with rilpivirine	C8214		HIV infection Initial treatment Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8214
	C8226		HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 8226
Dornase alfa	C5634		Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions	Compliance with Authority Required procedures - Streamlined

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			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.	Authority Code 5634
	C5635		Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years,AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Authority Required procedures - Streamlined Authority Code 5635
	C5740		Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must	Compliance with Authority Required procedures - Streamlined Authority Code 5740

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			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.	
	C9591		Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR 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 Authority Required procedures - Streamlined Authority Code 9591
	C9592		Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Authority Required procedures - Streamlined Authority Code 9592
	C9624		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	Compliance with Authority Required procedures - Streamlined

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			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.	Authority Code 9624
Doxorubicin - Pegylated Liposomal	C6234		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6234
	C6274		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 6274
	C9223		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 9223
	C9287		Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement.	Compliance with Authority Required procedures - Streamlined Authority Code 9287
Eculizumab	C6626	P6626	Atypical haemolytic uraemic syndrome (aHUS) Initial treatment Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to	Compliance with Written Authority Required procedures

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			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. 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) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy consistent with aHUS;	

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			(b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. The authority application must be in writing and must include: (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 detailed cover letter from the prescriber; and (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and (6) A measurement of body weight at the time of application; and (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, underInitial treatment 1-balance of supply; and	

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			(9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and (10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and (11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.	
	C6637	P6637	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. 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	Compliance with Written Authority Required procedures

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			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. 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 detailed cover letter from the prescriber; and (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and (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 before commencing eculizumab treatment, 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, if applicable; and (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with	

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			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.	
	C6642	P6642	Atypical haemolytic uraemic syndrome (aHUS) Initial treatment - Balance of Supply 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. 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. 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 Written Authority Required procedures
	C6668	P6668	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	Compliance with Written Authority Required procedures

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			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. 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	

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			treatment; and (3) A detailed cover letter from the prescriber; and (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and (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 before recommencing eculizumab treatment, 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, if applicable; and (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and (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.	
	C6686	P6686	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; AND Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised	Compliance with Written Authority Required procedures

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			eculizumab for this condition; AND Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR Patient must have severe TMA-related neurological impairment; OR Patient must have severe TMA-related gastrointestinal impairment; OR Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a 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	

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			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 detailed cover letter from the prescriber; and (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and (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 before commencing eculizumab treatment, 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 (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and (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	

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			deemed to have failed to respond to treatment with eculizumab.	
	C6687	P6687	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. 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	Compliance with Written Authority Required procedures

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			(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 detailed cover letter from the prescriber; and (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and (6) A measurement of body weight at the time of application, 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 following the treatment break, 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) 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; (13) Evidence that the patient has had a treatment response to their previous treatment with 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) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting	

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			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.	
	C6688	P6688	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 condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. 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	Compliance with Written Authority Required procedures

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			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 detailed cover letter from the prescriber; and (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and (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 before recommencing eculizumab treatment, 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, if applicable; and (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and (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	

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			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 Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Eltrombopag	C6724		Severe thrombocytopenia Initial treatment 2 - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must not have had a splenectomy; AND Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; AND Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy; AND Patient must be unsuitable for splenectomy due to medical reasons; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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 this drug will be authorised under this criterion.	
	C6725		Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult. For the purposes of this restriction, a sustained platelet response is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The platelet count must be no more than one month old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.	Compliance with Written Authority Required procedures
	C6738		Severe thrombocytopenia Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Patient must be an adult.	
	C6739		Severe thrombocytopenia Initial treatment 1 - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have had a splenectomy; AND Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy; AND Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. 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 Written 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 this drug will be authorised under this criterion.	
	C6790		Severe thrombocytopenia Second or subsequent Continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a continuing response to treatment with this drug; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult. For the purpose of this restriction, a continuing response to treatment with drug is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. The platelet count must be no more than one month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone	Compliance with Authority Required procedures
Emtricitabine with rilpivirine with tenofovir alafenamide	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Emtricitabine with tenofovir alafenamide	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be in combination with other antiretroviral agents.	Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Enfuvirtide	C5014		HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Authority Required procedures - Streamlined Authority Code 5014
Entecavir	C4993		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.	Compliance with Authority Required procedures - Streamlined Authority Code 4993
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5036

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5037		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have failed lamivudine, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5037
	C5044		Chronic hepatitis B infection Patient must not have cirrhosis, AND Patient must have failed lamivudine, AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 5044
Epoetin Alfa	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Epoetin Beta	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Epoetin lambda	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Epoprostenol	C10228		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10240		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	Compliance with Written Authority Required procedures

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			PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C10241		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
Etanercept	C9384		Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C9417		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply	Compliance with 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. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
	C10548		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C10578		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with Written 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 medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10579		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.	Compliance with Written Authority Required procedures

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			Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10599		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

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 Authority Required procedures - Streamlined Authority Code 5014
Everolimus	C5554		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5554
	C5795		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5795
	C9691		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9691
	C9693		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9693
Filgrastim	C6621		Severe chronic neutropenia Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR Patient must have neutrophil dysfunction; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 6621

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C6640		Chronic cyclical neutropenia Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 6640
	C6653		Mobilisation of peripheral blood progenitor cells The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6653
	C6654		Mobilisation of peripheral blood progenitor cells The treatment must be in a normal volunteer for use in allogeneic transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 6654
	C6655		Assisting autologous peripheral blood progenitor cell transplantation The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 6655
	C6679		Assisting bone marrow transplantation Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 6679
	C6680		Severe congenital neutropenia Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.	Compliance with Authority Required procedures - Streamlined Authority Code 6680

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C7822		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7843		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7843
	C8667		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 8667
	C8668		Mobilisation of peripheral blood progenitor cells The treatment must be in a normal volunteer for use in allogeneic transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 8668
	C8669		Severe congenital neutropenia Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.	Compliance with Authority Required procedures - Streamlined Authority Code 8669

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C8670		Severe chronic neutropenia Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR Patient must have neutrophil dysfunction; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 8670
	C8671		Assisting bone marrow transplantation Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 8671
	C8672		Mobilisation of peripheral blood progenitor cells The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 8672
	C8673		Chronic cyclical neutropenia Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 8673
	C8674		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 8674
	C8696		Assisting autologous peripheral blood progenitor cell transplantation The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.	Compliance with Authority Required procedures - Streamlined Authority Code 8696
Fosamprenavir	C4454		HIV infection	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Ganciclovir	C4972		Cytomegalovirus disease Prophylaxis Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 4972
	C4999		Cytomegalovirus disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 4999
	C5000		Cytomegalovirus retinitis Patient must be severely immunocompromised, including due to HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 5000
	C9404		Cytomegalovirus disease Prophylaxis Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9404
	C9526		Cytomegalovirus disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9526
Glecaprevir with pibrentasvir	C7593	P7593	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 8 weeks.	
	C7615	P7615	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures
	C10268	P10268	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 16 weeks. The application must include details of the prior treatment regimen containing an NS5A inhibitor.	Compliance with Authority Required procedures
Grazoprevir with elbasvir	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures
	C6625	P6625	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			and cirrhotic status; AND The treatment must be limited to a maximum duration of 16 weeks.	
Ibandronic acid	C5291		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5291
	C9333		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9333
Iloprost	C10228		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10229		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10284		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.	
Infliximab	C4524		Acute severe ulcerative colitis Must be treated by a gastroenterologist; OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology]. Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR	Compliance with Authority Required procedures - Streamlined Authority Code 4524

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital. Patient must be 6 years of age or older. For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where: (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood. For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours. At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.	
	C7777		Complex refractory Fistulising Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the first continuing	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).	
	C8296		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 first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND 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 Authority Required procedures
	C8644		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8645		Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 22 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8646		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment; AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Patient must be aged 18 years or older.	Compliance with Authority Required procedures
	C8715		Severe active rheumatoid arthritis Initial 1 (new patient)	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 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. 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	

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			agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of	

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			response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8743		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 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. 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	Compliance with Written Authority Required procedures

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			destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C8744		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND	Compliance with Written Authority Required procedures

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			Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition	

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			5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8745		Severe active rheumatoid arthritis Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Patient must be aged 18 years or older.	Compliance with Authority Required procedures
	C8755		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:	Compliance with Authority Required procedures - Streamlined Authority Code 8755

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			(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.	
	C8800		Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and	Compliance with Written Authority Required procedures

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			(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C8801		Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at	Compliance with Written Authority Required procedures

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			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. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of	

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			response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C8844		Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 8844

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			A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8881		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed	Compliance with Written Authority Required procedures

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			at baseline. The most recent PASI assessment must be no more than 1 month old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8883		Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.	Compliance with Authority Required procedures

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			The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8885		Severe chronic plaque psoriasis Initial 1 - Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 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 The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C8886		Severe chronic plaque psoriasis Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Must be treated by a dermatologist.	Compliance with Authority Required procedures
	C8940		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	procedures - Streamlined Authority Code 8940
	C8941		Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.	Compliance with Written 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. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The most recent PASI assessment must be no more than 1 month old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8962		Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C8983		Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
	C9065		Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.	Compliance with Written 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 treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9067		Severe psoriatic arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement,	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9068		Severe psoriatic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.	
	C9110		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (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.	Compliance with Written Authority Required procedures

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 quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9111		Severe psoriatic arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.	Compliance with Authority Required procedures
	C9169		Severe psoriatic arthritis	Compliance with Written Authority

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9188		Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:	Compliance with Authority Required procedures - Streamlined Authority Code 9188

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). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9191		Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9400		Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)	Compliance with Written Authority Required procedures

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 medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. 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.	

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			All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9401		Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes 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. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Up to a maximum of 3 repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9402		Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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. All measurements provided must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9472		Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as:	Compliance with Authority Required procedures - Streamlined Authority Code 9472

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9481		Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or	Compliance with Authority Required procedures - Streamlined Authority Code 9481

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			(c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9487		Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
	C9558		Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			3 months; AND Patient must not receive more than 18 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes 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. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3	

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			doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Up to a maximum of 3 repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9559		Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment; AND The treatment must provide no more than the balance of up to 18 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 ankylosing spondylitis.	Compliance with Authority Required procedures
	C9584		Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Authority Required procedures - Streamlined Authority Code 9584

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9587		Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (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. All measurements provided must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9602		Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 9602

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			The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9621		Ankylosing spondylitis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first	Compliance with Authority Required procedures - Streamlined Authority Code 9621

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

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.	
	C9675		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years. Patient must be 6 years of age or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9676		Severe Crohn disease First continuing treatment	Compliance with Written 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)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.	
	C9677		Complex refractory Fistulising Crohn disease Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application.	Compliance with Written Authority Required procedures

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

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.	
	C9731		Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 9731

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be aged 18 years or older. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9732		Complex refractory Fistulising Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.	Compliance with Authority Required procedures - Streamlined Authority Code 9732
	C9733		Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR	Compliance with Authority Required procedures - Streamlined Authority Code 9733

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9751		Moderate to severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C9752		Moderate to severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition. The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C9754		Moderate to severe ulcerative colitis Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.	
	C9756		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			the following: (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9759		Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of the most recent clinical assessment.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.	
	C9775		Moderate to severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND Patient must have a total PCDAI score of 30 points or less; AND	Compliance with Authority Required procedures - Streamlined Authority Code 9775

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. Patient must be aged 6 to 17 years inclusive. The PCDAI assessment must be no more than 1 month old at the time of prescribing. The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy. Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.	
	C9776		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years). Patient must be 6 years of age or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. An application for the continuing treatment must be accompanied with the assessment of response	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Department of Human Services website.	
	C9778		Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Applications for authorisation must be made in writing and must include: (a) 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. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. 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	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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 first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9779		Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.	
	C9781		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9783		Complex refractory Fistulising Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.	Compliance with Written Authority Required procedures

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, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.	
	C9785		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 9785

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C9787		Complex refractory Fistulising Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND Patient must have demonstrated an adequate response to treatment with this drug. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.	Compliance with Authority Required procedures - Streamlined Authority Code 9787
	C9788		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9799		Moderate to severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction. Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C9800		Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years). Patient must be 6 years of age or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application. Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis. A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Department of Human Services	

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			website.	
	C9803		Complex refractory Fistulising Crohn disease Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 1 month old at the time of application. Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C9806		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician; OR Must be treated by a specialist paediatric gastroenterologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years. Patient must be 6 years of age or older. Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 9806

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			If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9877		Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9900		Complex refractory Fistulising Crohn disease Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. Applications for authorisation must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.	
	C9975		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Authority Required procedures - Streamlined Authority Code 9975

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			(b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.	
	C9994		Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 22 weeks of treatment under this restriction. Patient must be aged 18 years or older. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
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	Compliance with Authority Required procedures - Streamlined

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			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.	Authority Code 4993
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5036
	C5042		Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Authority Required procedures - Streamlined Authority Code 5042
	C9259		Chronic Myeloid Leukaemia (CML) The condition must be Philadelphia chromosome positive.	Compliance with Authority Required procedures - Streamlined Authority Code 9259
Interferon Gamma-1b	C6222		Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6222
	C9639		Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Authority Required procedures - Streamlined Authority Code 9639
Ivacaftor	C9889		Cystic fibrosis Continuing treatment Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND	Compliance with Written 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 ivacaftor, given concomitantly with standard therapy, for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 12 months or older. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: 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;	

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			and (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.	
	C9890		Cystic fibrosis 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 Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged 12 months or older. Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: 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 copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and (4) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (6) sweat chloride result; and (7) height and weight measurements at the time of application; and (8) 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 Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
	C4993		Chronic hepatitis B infection	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	Required procedures - Streamlined Authority Code 4993
	C5036		Chronic hepatitis B infection Patient must have cirrhosis, AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5036
Lamivudine with zidovudine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Lanreotide	C4575		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Authority Required procedures - Streamlined Authority Code 4575
	C7025		Acromegaly The condition must be active; AND	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.	procedures - Streamlined Authority Code 7025
	C7042		Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.	Compliance with Authority Required procedures - Streamlined Authority Code 7042
	C7509		Functional carcinoid tumour Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND 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	Compliance with Authority Required procedures - Streamlined Authority Code 7509

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	
	C7532		Acromegaly Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND 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; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.	Compliance with Authority Required procedures - Streamlined Authority Code 7532
	C9225		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	Compliance with Authority Required procedures - Streamlined Authority Code 9225

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.	
	C9260		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9260
	C9261		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; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.	Compliance with Authority Required procedures - Streamlined Authority Code 9261
	C10061		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Required procedures - Streamlined Authority Code 10061
	C10075		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10075
	C10077		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10077
Lanthanum	C5530		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5530

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C9762		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9762
Ledipasvir with sofosbuvir	C5944	P5944	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 8 weeks.	Compliance with Authority Required procedures
	C5969	P5969	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures
	C5972	P5972	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks.	Compliance with Authority Required procedures
Lenalidomide	C4282		Myelodysplastic syndrome Continuing treatment Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			System (IPSS); AND Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome; AND Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide; AND 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		Myelodysplastic syndrome Initial treatment The treatment must be limited to a maximum duration of 16 weeks; AND Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS); AND Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND Patient must be red blood cell transfusion dependent. Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias. Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations: 1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR 5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias. 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.	
	C10334		Multiple myeloma Initial treatment with lenalidomide monotherapy in newly diagnosed disease	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be as monotherapy; AND The condition must be confirmed by a histological diagnosis; AND Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma; AND Patient must not have progressive disease following autologous stem cell transplant (ASCT). 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, the date the autologous stem cell transplant was performed, and nomination of which disease activity parameters will be used to assess progression. To enable confirmation of eligibility for treatment, the results of 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 progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C10335		Multiple myeloma Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have demonstrated progressive disease; AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be as monotherapy. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C10349		Multiple myeloma Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma; AND The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.	Compliance with Authority Required procedures
	C10350		Multiple myeloma Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease The condition must be confirmed by a histological diagnosis; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must have undergone or be ineligible for a primary stem cell transplant; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and (3) 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	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.	
	C10373		Multiple myeloma Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND Patient must be ineligible for a primary stem cell transplantation; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND The treatment must be in combination with dexamethasone. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and (3) a signed patient acknowledgement. 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C10427		Multiple myeloma Continuing treatment until progression in patients initiated on dual combination therapy (lenalidomide and dexamethasone), or, in patients initiated on triple therapy (lenalidomide, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond Patient must have previously been authorised with a PBS prescription with this drug for the condition; AND Patient must not have demonstrated progressive disease; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND The treatment must be in combination with dexamethasone. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C10428		Multiple myeloma Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must not have been treated with lenalidomide or bortezomib for this condition; AND The treatment must not exceed a total of 4 cycles under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response. To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be declared to be held on the patient's	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			medical records. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
	C10429		Multiple myeloma Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles) Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND The treatment must not exceed a total of 2 cycles under this restriction. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	Compliance with Authority Required procedures
	C10452		Multiple myeloma Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles) Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND The treatment must not exceed a total of 4 cycles under this restriction. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	Compliance with Authority Required procedures
	C10453		Multiple myeloma Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must not have been treated with lenalidomide or bortezomib for this condition; AND The treatment must not exceed a total of 4 cycles under this restriction.	Compliance with Written Authority Required procedures

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 Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response. To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be declared to be held on the patient's medical records. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
Levodopa with carbidopa	C10138	P10138	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic.	Compliance with Authority Required procedures - Streamlined Authority Code 10138
	C10161	P10161	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic.	Compliance with Authority Required procedures - Streamlined Authority Code 10161

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C10363	P10363	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 10363
	C10375	P10375	Advanced Parkinson disease Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND The treatment must be commenced in a hospital-based movement disorder clinic; AND Patient must require continuous administration of levodopa without an overnight break; OR Patient must require a total daily dose of more than 2000 mg of levodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 10375
Lipegfilgrastim	C7822		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7843		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7843
	C9224		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 9224
	C9322		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Authority Code 9322
Lopinavir with ritonavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Lumacaftor with ivacaftor	C9857		Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition. Patient must be 12 years of age or older. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort. Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and (4) the result of a FEV1measurement performed within a month prior to the date of application. Note: FEV1must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1is measured; and (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (6) height and weight measurements at the time of application; and (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.	
	C9891		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be aged between 6 and 11 years inclusive. 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort. Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and (3) the result of a FEV1measurement 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 FEV1is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.	
	C9920		Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(CFTR) modulator therapy for this condition. Patient must be aged between 6 and 11 years inclusive. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort. Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and (4) the result of a FEV1measurement performed within a month prior to the date of application. Note: FEV1must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1is measured; and (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (6) height and weight measurements at the time of application; and (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.	
	C9943		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard therapy for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition. Patient must be 12 years of age or older. 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. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort. Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and (3) the result of a FEV1measurement 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 FEV1is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.	
	C10005		Cystic fibrosis Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND The treatment must be given concomitantly with standard therapy for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition. Patient must be 2 years of age or older. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort. Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and (4) the result of a FEV1measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1is measured; and (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (6) height and weight measurements at the time of application; and (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV1and hospitalisation dates prior to initiating treatment (where available) should be provided.	
	C10007		Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 2 years of age or older. 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. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort. Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and (3) the result of a FEV1measurement performed within one month prior to the date of application, if aged 6	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.	
Macitentan	C10228	P10228	Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10236	P10236	Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10285	P10285	Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).	Compliance with Written 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 on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10728	P10728	Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) Patient must have received their most recent course of PBS-subsidised dual therapy with this PAH agent and a phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. 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.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A maximum of 5 repeats may be requested.	
	C10845	P10845	Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be in combination with a PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments;	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10846	P10846	Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised phosphodiesterase-5 inhibitor (PDE-5i) for this condition prior to 1 October 2020; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10850	P10850	Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change)	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have had their most recent course of PBS-subsidised dual therapy with a phosphodiesterase-5 inhibitor (PDE-5i) and an endothelin receptor antagonist (ERA) other than this agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10869	P10869	Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with a phosphodiesterase-5 inhibitor (PDE-5i) for this condition; AND The treatment must be in combination with the PBS-subsidised PDE-5i for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil.	Compliance with 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. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
Mannitol	C7362		Cystic fibrosis The treatment must be as monotherapy; AND Patient must be intolerant or inadequately responsive to dornase alfa. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Authority Required procedures - Streamlined Authority Code 7362

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C7367		Cystic fibrosis The treatment must be in combination with dornase alfa; AND Patient must be inadequately responsive to dornase alfa; AND Patient must have trialled hypertonic saline for this condition. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (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 Authority Required procedures - Streamlined Authority Code 7367
	C9527		Cystic fibrosis The treatment must be as monotherapy; AND Patient must be intolerant or inadequately responsive to dornase alfa. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND	Compliance with Authority Required procedures - Streamlined Authority Code 9527

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(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.	
	C9593		Cystic fibrosis The treatment must be in combination with dornase alfa; AND Patient must be inadequately responsive to dornase alfa; AND Patient must have trialled hypertonic saline for this condition. Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (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 Authority Required procedures - Streamlined Authority Code 9593
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	Compliance with Authority Required procedures - Streamlined Authority Code 5008

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	
Mepolizumab	C9885	P9885	Uncontrolled severe eosinophilic asthma Balance of supply Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.	Compliance with Authority Required procedures
	C10221	P10221	Uncontrolled severe eosinophilic asthma Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.	

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			The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following: (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the eosinophil count and date; and (iv) Asthma Control Questionnaire (ACQ-5) score.	
	C10222	P10222	Uncontrolled severe eosinophilic asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following: (i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and (iii) eosinophil count and date; and (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy). An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine. At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator.	
	C10280	P10280	Uncontrolled severe eosinophilic asthma Continuing treatment Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 12 years or older. An adequate response to this biological medicine is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5. All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			corticosteroid dose, should be made at around 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug. Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment. A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS subsidised treatment with this biological medicine for severe asthma within the current treatment cycle. At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes: (i) details of maintenance oral corticosteroid dose; or (ii) a completed Asthma Control Questionnaire (ACQ-5) score.	
	C10483	P10483	Uncontrolled severe eosinophilic asthma Grandfather treatment - use in a patient initiated with non-PBS subsidised pre-filled syringe or pen device Patient must have received non-PBS-subsidised treatment with this biological medicine's pre-filled syringe or pen device for this PBS-indication prior to 1 June 2020; AND Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed with severe asthma by a multidisciplinary severe asthma clinic team; AND	Compliance with Written Authority Required procedures

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application (if not already provided). The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be declared to have been met at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; AND (b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator. An adequate response to this biological medicine is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form which seeks details of the following (if not already provided): (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and (ii) eosinophil pathology report (eosinophil counts and dates); and (iii) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose.	
	C10484	P10484	Uncontrolled severe eosinophilic asthma Grandfather treatment - use in a patient initiated with non-PBS-subsidised pre-filled syringe or pen device Patient must have received non-PBS-subsidised treatment with this biological medicine's pre-filled syringe or pen device for this PBS-indication prior to 1 June 2020; AND Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed with severe asthma by a multidisciplinary severe asthma clinic team; AND Patient must have had, prior to commencement of this drug, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR Patient must have had, prior to commencement of this drug, a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre prior to	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			commencement of a biological medicine treatment for severe asthma; OR Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to commencement of a biological medicine treatment for severe asthma; AND Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine; AND Patient must have failed to achieve adequate control with optimised asthma therapy prior to commencement of this biological medicine despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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 (if not already provided). The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be declared to have been met at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; AND (b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids)	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			prescribed/supervised by a physician. An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator. An adequate response to this biological medicine is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form which seeks details of the following (if not already provided): (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and (ii) eosinophil pathology report (eosinophil counts and dates); and (iii) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Methoxsalen	C10971	P10971	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Initial treatment Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. Patient must be aged 18 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 10971
	C10985	P10985	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Initial treatment Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. Patient must be aged 18 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 10985
	C10988	P10988	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6	Compliance with Authority Required procedures - Streamlined Authority Code 10988

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			months of treatment for the first time; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment	
	C10989	P10989	Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma Continuing treatment Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule. Must be treated by a haematologist; OR Must be treated by a medical physician working under the supervision of a haematologist. A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment	Compliance with Authority Required procedures - Streamlined Authority Code 10989
Methoxy polyethylene glycol-epoetin beta	C6294		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6294

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C9688		Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9688
Midostaurin	C8138	P8138	Acute Myeloid Leukaemia Maintenance therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance or the initial maintenance grandfathering treatment restriction; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not be undergoing or have undergone a stem cell transplant. A maximum of 9 cycles will be authorised under this restriction in a lifetime. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	Compliance with Authority Required procedures
	C8177	P8177	Acute Myeloid Leukaemia Maintenance therapy - Initial treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin; AND Patient must not be undergoing or have undergone a stem cell transplant; AND The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition. A maximum of 3 cycles will be authorised under this restriction in a lifetime.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; (2) a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and (3) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and (4) confirmation that the patient does not have progressive disease; and (5) a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and (6) a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.	
	C8193	P8193	Acute Myeloid Leukaemia Induction / Consolidation therapy Patient must not have received prior chemotherapy as induction therapy for this condition; OR The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy; AND The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition; AND The condition must not be acute promyelocytic leukaemia; AND The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition. A maximum of 6 cycles will be authorised under this restriction in a lifetime. Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline. The FLT3 ITD or TKD mutation test result and date of testing must be provided at the time of application.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.	
	C8218	P8218	Acute Myeloid Leukaemia Maintenance therapy - Grandfathered treatment Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin; AND Patient must not be undergoing or have undergone a stem cell transplant; AND The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition. A maximum of 2 cycles will be authorised under this restriction in a lifetime. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the maintenance therapy continuing treatment criteria. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The authority application must be made in writing and must include: (1) a completed authority prescription form; (2) a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and (3) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and (4) confirmation that the patient does not have progressive disease; and (5) a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and (6) a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.	
Mycophenolic Acid	C4084		Prophylaxis of renal allograft rejection Management The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required Procedures – Streamlined Authority Code 4084
	C4095		WHO Class III, IV or V lupus nephritis Management The condition must be proven by biopsy, Must be treated by a nephrologist or in consultation with a nephrologist. The name of the consulting nephrologist must be included in the patient medical records.	Compliance with Authority Required Procedures – Streamlined Authority Code 4095
	C5554		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5554
	C5600		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5600
	C5653		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must be under the supervision and direction of a transplant unit.	Authority Code 5653
	C5795		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5795
	C9689		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9689
	C9690		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9690
	C9691		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9691
	C9692		Prophylaxis of renal allograft rejection Management The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9692
	C9693		Management of cardiac allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9693
	C9809		WHO Class III, IV or V lupus nephritis Management The condition must be proven by biopsy. Must be treated by a nephrologist or in consultation with a nephrologist. The name of the consulting nephrologist must be included in the patient medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9809
Natalizumab	C9744		Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist.	Compliance with 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 disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.	Streamlined Authority Code 9744
	C9818		Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist. The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient. The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.	Compliance with Authority Required procedures - Streamlined Authority Code 9818

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Nevirapine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
	C4526		HIV infection Initial Patient must have been stabilised on nevirapine immediate release; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4526
Nusinersen	C7849		Spinal muscular atrophy (SMA) Initial treatment - Loading doses Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA. The condition must 5q homozygous deletion, mutation of, or compound heterozygous mutation in the SMN1 gene of type I, II or IIIa; AND Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; AND The treatment must be given concomitantly with standard of care for this condition; AND The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction. Patient must be 18 years of age or under. Defined signs and symptoms of type I SMA are: i) Onset before 6 months of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type II SMA are: i) Onset between 6 and 18 months; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Weakness in trunk righting/derotation; or v) Hypotonia; or vi) Absence of deep tendon reflexes; or vii) Failure to gain weight appropriate for age; or viii) Any active chronic neurogenic changes; or ix) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type IIIa SMA are: i) Onset between 18 months and 3 years of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital. Application for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Spinal muscular atrophy PBS Authority Application - Supporting Information Form which includes the following: i) specification of SMA type (I, II or IIIa); and (ii) sign(s) and symptom(s) that the patient has experienced; and (iii) patient's age at the onset of sign(s) and symptom(s).	
	C10112		Spinal muscular atrophy (SMA) Continuing treatment - Maintenance	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given concomitantly with standard of care for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.	
Ocrelizumab	C7386		Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 7386
	C7699		Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 7699

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	
	C9523		Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9523
	C9635		Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Must be treated by a neurologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9635
Octreotide	C5901		Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 5901

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C5906		Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 5906
	C6369		Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 6369
	C6390		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 6390
	C8161		Acromegaly The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND	Compliance with Authority Required procedures - Streamlined Authority Code 8161

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	
	C8165		Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 8165
	C8197		Acromegaly Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 8197
	C8198		Vasoactive intestinal peptide secreting tumour (VIPoma)	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Required procedures - Streamlined Authority Code 8198
	C8208		Functional carcinoid tumour Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 8208
	C9232		Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9232
	C9233		Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy	Compliance with Authority Required procedures - Streamlined Authority Code 9233

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			is contraindicated; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 times daily; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	
	C9262		Acromegaly The condition must be controlled with octreotide immediate release injections; AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND The treatment must cease if IGF1 is not lower after 3 months of treatment; AND The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Authority Required procedures - Streamlined Authority Code 9262
	C9288		Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9288
	C9289		Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and	Compliance with Authority Required procedures - Streamlined Authority Code 9289

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			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.	
	C9313		Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 9313
	C10061		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10061
	C10075		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	Compliance with Authority Required procedures - Streamlined Authority Code 10075
	C10077		Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) The condition must be unresectable locally advanced disease or metastatic disease; AND The condition must be World Health Organisation (WHO) grade 1 or 2; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be aged 18 years or older. WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less	Compliance with Authority Required procedures - Streamlined Authority Code 10077

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			than or equal to 2. WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.	
Omalizumab	C7046		Severe chronic spontaneous urticaria Continuing treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.	Compliance with Authority Required procedures
	C7055		Severe chronic spontaneous urticaria Initial treatment Must be treated by a clinical immunologist; OR Must be treated by an allergist; OR Must be treated by a dermatologist; OR Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU). The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria); AND Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines; AND Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy; AND Patient must not receive more than 12 weeks of treatment under this restriction. A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following: 1) a H2 receptor antagonist (150 mg twice per day); or 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or 3) doxepin (up to 25 mg three times a day) If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include: (i) demonstration of failure to achieve an adequate response to standard therapy; and (ii) drug names and doses of standard therapies that the patient has failed; and (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.	
	C9855		Uncontrolled severe allergic asthma Balance of supply in a patient aged 12 years or older Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.	Compliance with Authority Required procedures
	C10219		Uncontrolled severe allergic asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Allergic Asthma (omalizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following: (i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and (iii) the IgE results; and (iv) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this	

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			biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine. At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator.	
	C10223		Uncontrolled severe allergic asthma Balance of supply in a patient aged 6 to 12 years Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.	Compliance with Authority Required procedures
	C10226		Uncontrolled severe allergic asthma Continuing treatment Patient must have a documented history of severe allergic asthma; AND Patient must have demonstrated or sustained an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. An adequate response to omalizumab treatment is defined as:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of: (i) maintenance oral corticosteroid dose; and (ii) Asthma Control Questionnaire (ACQ-5) score; or (iii) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.	
	C10265		Uncontrolled severe allergic asthma Initial treatment	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE; AND Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; 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 6 to less than 12 years. Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician. Patient must be under the care of the same physician for at least 6 months. Optimised asthma therapy includes: (i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND (ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. 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 (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be	

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			used), AND (b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following: (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the IgE result; and (iv) Asthma Control Questionnaire (ACQ-5) score; or (v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C10279		Uncontrolled severe allergic asthma Continuing treatment Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be aged 12 years or older. 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 or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction). All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug. Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment. A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			within the current treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of: (i) maintenance oral corticosteroid dose; or (ii) Asthma Control Questionnaire (ACQ-5) score including the date of assessment of the patient's symptoms; or (iii) for patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the exacerbation rate has reduced.	
	C10299		Uncontrolled severe allergic asthma Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR Patient must have a diagnosis of asthma from at least two physicians experienced in the management of	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			patients with severe asthma; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old; AND Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The 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, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines for severe asthma within the same treatment cycle. A treatment break in PBS-subsidised omalizumab therapy of at least 6 months must be observed in a patient with uncontrolled severe allergic asthma, in whom omalizumab is the only appropriate treatment option, and who has either failed to achieve or sustain a response to the most recent PBS-subsidised omalizumab therapy. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. 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. A multidisciplinary severe asthma clinic team comprises of: A respiratory physician; and A pharmacist, nurse or asthma educator. 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 (date of commencement and duration of therapy); and (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (iii) the IgE result; and	

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			(iv) Asthma Control Questionnaire (ACQ-5) score.	
Pamidronic Acid	C4433		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy	Compliance with Authority Required procedures – Streamlined Authority Code 4433
	C5218		Multiple Myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5218
	C5291		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5291
	C9234		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9234
	C9315		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9315
	C9335		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9335
Pasireotide	C9088		Acromegaly Initial treatment Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; OR Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN); AND The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			tolerated according to the TGA approved Product Information; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. Patient must be aged 18 years or older. If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication. If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as: 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR 2) IGF-1 level is greater than the age- and sex-adjusted ULN. In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission. Biochemical evidence of remission is defined as: 1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1) The authority application must be made in writing and must include: a) a completed authority prescription form; and b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and d) a recent result of GH or IGF-1 levels must be provided.	
	C9089		Acromegaly Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be given concomitantly with PBS-subsidised pegvisomant. Patient must be aged 18 years or older. In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission. Biochemical evidence of remission is defined as:	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1) In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.	
Pegfilgrastim	C7822		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7822
	C7843		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 7843
	C9235		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia; OR Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 9235
	C9303		Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia; OR Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.	Compliance with Authority Required procedures - Streamlined Authority Code 9303
Peginterferon alfa-2a	C5004		Chronic hepatitis C infection Must be treated in an accredited treatment centre.	Compliance with Authority Required procedures -

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			Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age. Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND Patient must have a contraindication to ribavirin; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must be limited to a maximum duration of 48 weeks. Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.	Streamlined Authority Code 5004
	C9603		Chronic hepatitis C infection Must be treated in an accredited treatment centre. Patient must be aged 18 years or older; AND Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age. Patient must have compensated liver disease; AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND Patient must have a contraindication to ribavirin; AND The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND The treatment must be limited to a maximum duration of 48 weeks. Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 9603
Pegvisomant	C7087		Acromegaly Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue; AND The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose. Somatostatin analogues include octreotide, lanreotide and pasireotide In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission. Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1). In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.	
	C9041		Acromegaly Initial treatment Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN); AND The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information; AND The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue. Somatostatin analogues include octreotide, lanreotide and pasireotide Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as: 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR 2) IGF-1 level is greater than the age- and sex-adjusted ULN. If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication. If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission. Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1). Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information. The authority application must be made in writing and must include: a) two completed authority prescription forms ; and b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and d) a recent result of the IGF-1 level and the date of assessment ; and e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide No increase in the maximum quantity or number of units may be authorised for the loading dose.	
Plerixafor	C4549		Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; OR Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND Patient must have failed previous stem cell collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records	Compliance with Authority Required procedures - Streamlined Authority Code 4549
	C9329		Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; OR Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND Patient must have failed previous stem cell collection; OR Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR	Compliance with Authority Required procedures - Streamlined Authority Code 9329

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	
Pomalidomide	C7791		Multiple myeloma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have progressive disease; AND The treatment must be in combination with dexamethasone; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	Compliance with Authority Required procedures
	C7952		Multiple myeloma Initial treatment The treatment must be in combination with dexamethasone; AND Patient must have undergone or be ineligible for a primary stem cell transplant; AND Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. 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. If treatment with either bortezomib or lenalidomide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to either bortezomib or lenolidomide treatment develops during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and (3) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide; and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(4) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to bortezomib. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.	
Raltegravir	C4274		HIV infection Continuing The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have previously received PBS-subsidised therapy for HIV infection. Patient must be aged 2 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 4274
	C4275		HIV infection Initial The treatment must be in combination with other antiretroviral agents; AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease. Patient must be aged 2 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 4275
	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Ribavirin	C5957	P5957	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.	Compliance with Authority Required procedures
	C5958	P5958	Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 24 weeks. Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.	Compliance with Authority Required procedures
Rifabutin	C6350		Mycobacterium avium complex infection Patient must be human immunodeficiency virus (HIV) positive.	Compliance with Authority Required procedures - Streamlined Authority Code 6350
	C6356		Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 6356
	C9560		Mycobacterium avium complex infection Patient must be human immunodeficiency virus (HIV) positive.	Compliance with Authority Required procedures - Streamlined Authority Code 9560

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C9622		Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 9622
Rilpivirine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Riociguat	C6645		Chronic thromboembolic pulmonary hypertension (CTEPH) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must demonstrate stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be aged 18 years or older. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (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 each written continuing	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. 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 this drug is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease. The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment. A maximum of 5 repeats will be authorised. Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.	
	C6664		Chronic thromboembolic pulmonary hypertension (CTEPH) Initial treatment Patient must have WHO Functional Class II, III or IV CTEPH; AND The condition must be inoperable by pulmonary endarterectomy; OR The condition must be recurrent or persistent following pulmonary endarterectomy; AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be aged 18 years or older.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			CTEPH that is inoperable by pulmonary endarterectomy is defined as follows: Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm-5measured at least 90 days after start of full anticoagulation; and A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation. CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows: RHC demonstrating a PVR of greater than 300 dyn*sec*cm-5measured at least 180 days following pulmonary endarterectomy. Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application. Applications for authorisation must be in writing and must include:(1) completed authority prescription forms sufficient for dose titration; and(2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available:(i) RHC composite assessment, and(ii) ECHO composite assessment, and(iii) 6 Minute Walk Test (6MWT); and(3) a signed patient acknowledgment form; and(4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or(5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or(6) confirmation of an echocardiogram demonstrating right ventricular dysfunction. Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) RHC plus ECHO composite assessments;(2) RHC composite assessment plus 6MWT;(3) RHC composite assessment only. In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:(1) ECHO composite assessment plus 6MWT;(2) ECHO composite assessment only. 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. Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, the quantity	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats. The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated. 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.	
	C7629		Chronic thromboembolic pulmonary hypertension (CTEPH) Balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction; AND The treatment must be the sole PBS-subsidised agent for this condition. Must be treated in a centre with expertise in the management of CTEPH. Patient must be aged 18 years or older.	Compliance with Authority Required procedures
	C10231		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10243		Pulmonary arterial hypertension (PAH)	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Initial 2 (change) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.	Required procedures
	C10245		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.	Compliance with Written 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. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.	
Ritonavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Rituximab	C7021		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 The authority application must be made in writing	Compliance with Written Authority Required procedures
	C7022		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.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			This drug is not PBS-subsidised for maintenance therapy. The authority application must be made in writing	
	C9336		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 Authority Required procedures - Streamlined Authority Code 9336
	C9340		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C9344		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; 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 The authority application must be made in writing	Compliance with Written Authority Required procedures
	C9446		Severe active rheumatoid arthritis	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	Required procedures - Streamlined Authority Code 9446
	C9448		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 2 infusions of this drug under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.	
	C9449		Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 2 infusions of this drug under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.	
	C9450		Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 2 infusions of this drug under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C9511		Severe active microscopic polyangiitis Induction of remission The treatment must be for the induction of remission; AND Patient must not have previously received this drug for this condition; AND The treatment must in combination with glucocorticoids; AND Patient must be at risk of end-organ damage or mortality; AND Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide. Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology. This drug is not PBS-subsidised for maintenance therapy. The authority application must be made in writing	Compliance with Written Authority Required procedures
	C9512		Severe active rheumatoid arthritis	Compliance with Written Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR 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 this drug under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. 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	Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.	
	C9539		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 Authority Required procedures - Streamlined Authority Code 9539
	C9611		Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 9611

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			An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C9640		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 Authority Required procedures - Streamlined Authority Code 9640
	C9641		Severe active microscopic polyangiitis	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	Required procedures - Streamlined Authority Code 9641
Romiplostim	C6694		Severe thrombocytopenia Initial treatment 1 - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have had a splenectomy; AND Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy; AND Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application. Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Authority approval will not be given for doses higher than 10 micrograms/kg/week The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a 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.	
	C6737		Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult. For the purposes of this restriction, a sustained platelet response is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses higher than 10 micrograms/kg/week Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			PBS-subsidised treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form , and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The platelet count must be no more than one month old at the time of application.	
	C6738		Severe thrombocytopenia Initial 1, Initial 2, First Continuing treatment or Re-initiation of interrupted treatment, and Second and Subsequent Continuing treatment - balance of supply The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Patient must be an adult.	Compliance with Authority Required procedures
	C6766		Severe thrombocytopenia Initial treatment 2 - New patient The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must not have had a splenectomy; AND Patient must have failed to acheive an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; AND Patient must have failed to acheive an adequate response to, or be intolerant to, immunoglobulin therapy; AND Patient must be unsuitable for splenectomy due to medical reasons; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be an adult. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application; (a) a platelet count of less than or equal to 20,000 million per L; OR (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range. At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application. Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. Authority approval will not be given for doses higher than 10 micrograms/kg/week The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a 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.	
	C6789		Severe thrombocytopenia Second or Subsequent Continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a continuing response to treatment with this drug; AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition. Patient must be an adult.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For the purpose of this restriction, a continuing response to treatment with drug is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. The platelet count must be no more than 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. Authority approval will not be given for doses higher than 10 micrograms/kg/week Authority applications for second and subsequent periods of continuing therapy may be made by telephone	
Saquinavir	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4512
Sevelamer	C5530		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5530
	C9762		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND	Compliance with Authority Required procedures - Streamlined

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Authority Code 9762
Sildenafil	C10228		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10234		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10304		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10726		Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10732		Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy)	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent and an endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. 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.	
	C10797		Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised endothelin receptor antagonist (ERA) for this condition prior to 1 October 2020; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10848		Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have had their most recent course of PBS-subsidised dual therapy with an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i) other than this agent for this condition.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10868		Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with an endothelin receptor antagonist (ERA) for this condition; AND The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
Sirolimus	C5795		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 5795
	C9914		Management of renal allograft rejection Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9914
Sofosbuvir with velpatasvir	C5969		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks.	Compliance with Authority Required procedures
Sofosbuvir with velpatasvir and voxilaprevir	C10248		Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 12 weeks. The application must include details of the prior treatment regimen containing an NS5A inhibitor.	
Sucroferric oxyhydroxide	C5530		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5530
	C9762		Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9762
Tacrolimus	C5569		Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Authority Required procedures - Streamlined Authority Code 5569
	C9697		Management of rejection in patients following organ or tissue transplantation The treatment must be under the supervision and direction of a transplant unit; AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Authority Required procedures - Streamlined Authority Code 9697

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Tadalafil	C10228		Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	Compliance with Authority Required procedures
	C10234		Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A maximum of 5 repeats may be requested.	
	C10304		Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (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:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10726		Pulmonary arterial hypertension (PAH) Initial 1 (dual therapy - previously untreated patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10731		Pulmonary arterial hypertension (PAH) Initial 2 (dual therapy - previously treated patients) Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have documented a failure to achieve or maintain WHO Functional Class II status with prior PBS-subsidised monotherapy treatment with an endothelin receptor antagonist (ERA) for this condition; AND The treatment must be in combination with a PBS-subsidised endothelin receptor antagonist (ERA) for this condition.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10732		Pulmonary arterial hypertension (PAH) Continuing treatment (dual therapy) Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent and an endothelin receptor antagonist (ERA) for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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.	
	C10733		Pulmonary arterial hypertension (PAH) Grandfathered patients (dual therapy) Patient must be receiving dual therapy with this non PBS-subsidised pulmonary arterial hypertension (PAH) agent and a non PBS-subsidised endothelin receptor antagonist (ERA) for this condition prior to 1 October 2020; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
	C10799		Pulmonary arterial hypertension (PAH) Initial 3 (dual therapy - change) Patient must have had their most recent course of PBS-subsidised dual therapy with an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i) other than this agent for this condition. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat. For the purposes of PBS subsidy, dual therapy refers to combined use of an endothelin receptor antagonist (ERA) and a phosphodiesterase-5 inhibitor (PDE-5i). (i) An ERA includes bosentan monohydrate, or macitentan. (ii) A PDE-5i includes sildenafil citrate, or tadalafil. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Once patients are approved dual therapy with a PAH agent from the PDE-5i class; or a PAH agent from the ERA class, they may swap between PAH agents within the same class. This means that patients may commence treatment with another PAH agent in the same class, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. Applications to swap within a PAH agent class must be made under the relevant initial treatment restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested.	
Teduglutide	C9515		Type III Short bowel syndrome with intestinal failure Initial treatment or initial grandfather treatment - balance of supply Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment with this drug for this condition as a grandfathered patient; AND Patient must have received insufficient therapy with this drug under the initial or grandfather treatment restriction to complete the maximum duration of 12 months of initial treatment; AND The treatment must provide no more than the balance of up to 12 months of treatment.	Compliance with Authority Required procedures
	C9569		Type III Short bowel syndrome with intestinal failure Initial treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have short bowel syndrome with intestinal failure following major surgery; AND Patient must have a history of dependence on parenteral support for at least 12 months; AND Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks; AND Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years; AND The treatment must not exceed 12 months under this restriction; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Baseline is the mean number of days of parenteral support per week over the four weeks immediately prior to initiating treatment with teduglutide under the PBS initial treatment restriction or four weeks immediately prior to initiating treatment with non-PBS subsidised teduglutide for grandfathered patients. A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs. Baseline number of days of parenteral support should be documented in the patient's medical records. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure form; and (3) details of baseline mean number of days on parenteral support per week for 4 consecutive weeks immediately preceding this application; and (4) documented duration in months of prior dependence on parenteral support.	
	C9687		Type III Short bowel syndrome with intestinal failure Initial treatment - Grandfathered patients Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2019; AND Patient must have short bowel syndrome with intestinal failure following major surgery; AND Patient must have had a history of dependence on parenteral support for at least 12 months prior to initiating non-PBS subsidised treatment with this drug for this condition; AND Patient must have received a stable parenteral support regimen for at least 3 days per week in the 4 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition; AND Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years; AND Patient must have achieved a treatment response if the patient has been on non-PBS subsidised therapy with this drug for more than 12 months. Baseline is the mean number of days of parenteral support per week over the 4 weeks immediately prior to initiating treatment with non-PBS subsidised teduglutide for grandfathered patients. A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs. A patient has met the criteria for treatment response when there is a reduction in the mean number of days of parenteral support of at least 1 day per week since initiating non-PBS subsidised treatment, or where a patient has completely ceased treatment with parenteral support for a period of at least 4 consecutive weeks prior to application for PBS-subsidised treatment. The number of days of parenteral support is calculated as the mean number of days in which any	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs between commencement of non-PBS subsidised teduglutide and application for PBS-subsidised treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure Grandfather PBS Authority Application - Supporting Information Form; and (3) details of non-PBS subsidised teduglutide treatment start date; and (4) details of the mean number of days on parenteral support per week for 4 consecutive weeks prior to initiating non-PBS subsidised therapy; and (5) documented duration in months of dependence on parenteral support prior to initiating non-PBS subsidised treatment; and (6) details of response to teduglutide treatment if patient has received 12 or more months of non-PBS subsidised treatment. A patient may qualify for PBS-subsidised treatment under this restriction once only. For patients who have been on this drug for less than 12 months, the maximum number of repeats that will be approved will be for an amount equivalent to an initial 12 month supply of PBS and non-PBS subsidised treatment. For patients who have been on this drug for more than 12 months, a maximum of 5 repeats will be approved. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the First continuing treatment criteria.	
	C9740		Type III Short bowel syndrome with intestinal failure Subsequent continuing treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have received PBS-subsidised first-continuing treatment with this drug for this condition and achieved a treatment response in the preceding treatment period; OR Patient must have received PBS-subsidised recommencement of treatment following a trial cessation period and not have previously experienced a failure to respond to treatment with this drug for this condition. Treatment response For applications for subsequent continuing treatment, treatment response is when there was a reduction in the mean number of days of parenteral support of at least 1 day per week since the last assessment for	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			PBS-subsidised treatment, OR where a patient has completely ceased treatment with parenteral support for a period of at least 4 consecutive weeks. The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period Treatment failure For applications for subsequent continuing treatment, failure of treatment is defined as an increase in the mean number of days per week of parenteral support requirements of at least 1 day per week over the preceding 4 week period compared to the last assessment for PBS-subsidised treatment of parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs. Patients who experience failure of treatment must permanently discontinue treatment. Treatment stability Patients who neither demonstrate a treatment response nor a treatment failure since the last assessment for PBS-subsidised treatment are considered to have a stable parenteral support regimen, defined as the same mean number of days of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the 4 weeks preceding treatment period, where the number of days is greater than zero and the mean number of days of parenteral support is less than baseline. Patients with a stable parenteral support regimen over 6 months must undertake a trial cessation period. Patients who have re-commenced after a trial cessation period are exempt from further trial cessation. Trial cessation period Patients who demonstrate a stable frequency of mean days per week of parenteral support in a 6-month period commencing after the initial 12 months of treatment with this drug for this condition are required to undertake a trial of treatment cessation. Patients who have re-commenced after a trial cessation period are exempt from further trial cessation. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure Form; and (3) details of the mean number of days reduction of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the preceding treatment period or confirmation the patient has had 4 consecutive weeks without parenteral support (if applicable); and (4) the current mean number of days per week of parenteral support over the preceding 4 week period.	
	C9793		Type III Short bowel syndrome with intestinal failure First continuing treatment	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; OR Patient must have received PBS-subsidised treatment with this drug for this condition as a grandfathered patient; AND Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline. Baseline is the mean number of days of parenteral support per week over the four weeks immediately prior to initiating treatment with teduglutide under the PBS initial treatment restriction or four weeks immediately prior to initiating treatment with non-PBS subsidised teduglutide for grandfathered patients. The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period Treatment failure For applications for first continuing treatment, failure of treatment is defined as no change compared to baseline in the mean number of days per week in parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs. Patients who experience failure of treatment must permanently discontinue treatment. Current mean number of days of parenteral support should be documented in the patient's medical records. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure Form; and (3) details of the mean number of days reduction of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs from baseline; and (4) the current mean number of days per week of parenteral support over the preceding 4 week period.	
	C9829		Type III Short bowel syndrome with intestinal failure Recommencement of treatment Must be treated by a gastroenterologist; OR Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit. Patient must have received PBS-subsidised treatment with this drug for this condition; AND Patient must have undertaken a trial cessation period due to experiencing a stable parenteral support regimen in the first continuing or subsequent continuing treatment phase, and not due to a treatment failure; AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have experienced deterioration during a trial cessation period. Trial cessation period Patients who demonstrate a stable frequency of mean days per week of parenteral support in a 6-month period commencing after the initial 12 months of treatment with this drug for this condition are required to undertake a trial of treatment cessation. Patients who have re-commenced after a trial cessation period are exempt from further trial cessation. Deterioration during the trial cessation period includes an increase in parenteral support frequency of more than or equal to one day per week from the pre-cessation level, or other clinical parameters suggestive of deterioration including changes in renal function or urinary sodium levels or changes in body weight. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Short bowel syndrome with intestinal failure Form; and (3) details of the reason for recommencement after trial cessation; and (4) the current mean number of days per week of parenteral support over the preceding 4 week period (5) details of completion of the trial cessation period including the start and end date.	
Tenofovir	C6980	P6980	Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have detectable HBV DNA; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 6980
	C6982	P6982	HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6982
	C6983	P6983	Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a	Compliance with Authority Required procedures - Streamlined Authority Code 6983

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			transplant unit prior to initiating therapy.	
	C6984	P6984	Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.	Compliance with Authority Required procedures - Streamlined Authority Code 6984
	C6992	P6992	Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 6992
	C6998	P6998	HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6998
	C10362	P10362	Chronic hepatitis B infection Patient must be in the third trimester of pregnancy; AND Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection.	Compliance with Authority Required procedures - Streamlined Authority Code 10362
Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4470

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C4522		HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Tenofovir with emtricitabine	C6985		HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6985
	C6986		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures - Streamlined Authority Code 6986
Tenofovir with emtricitabine and efavirenz	C4470		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection	Compliance with Authority Required procedures - Streamlined Authority Code 4470
	C4522		HIV infection Initial Patient must be antiretroviral treatment naïve	Compliance with Authority Required procedures - Streamlined Authority Code 4522
Tezacaftor with ivacaftor and ivacaftor	C9880		Cystic fibrosis - homozygous for the F508del mutation Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition. Patient must be 12 years of age or older. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort; Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin; Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and (3) the result of a FEV1measurement 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 FEV1is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.	
	C9961		Cystic fibrosis - homozygous for the F508del mutation Initial treatment	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities. Patient must be 12 years of age or older. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort; Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin; Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and (4) the result of a FEV1measurement performed within a month prior to the date of application. Note: FEV1must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1is measured; and (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (6) height and weight measurements at the time of application; and (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months. For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV1and hospitalisation dates prior to initiating treatment (where available) should be provided.	
	C10064		Cystic fibrosis - one residual function (RF) mutation Initial treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation. Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition; AND Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities. Patient must be 12 years of age or older. The patient must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers: Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort; Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin; Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide. The authority application must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and (3) a copy of the pathology report detailing the molecular testing for the patient having at least one RF mutation on the CFTR gene; and (4) the result of a FEV_1measurement performed within a month prior to the date of application. Note: FEV_1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time $FEV_1$is measured; and (5) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (6) height and weight measurements at the time of application; and (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months. For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline $FEV_1$and hospitalisation dates prior to initiating treatment (where available) should be provided.	
	C10069		Cystic fibrosis - one residual function (RF) mutation Continuing treatment	Compliance with Written Authority Required procedures

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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and (3) the result of a FEV_1measurement performed within a month prior to the date of application. Note: FEV_1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time $FEV_1$is measured; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and (5) height and weight measurements at the time of application; and (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.	
Thalidomide	C5914		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5914
	C9290		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9290
Tipranavir	C5764		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 Authority Required procedures - Streamlined Authority Code 5764
Tocilizumab	C8627		Severe active rheumatoid arthritis Continuing Treatment - balance of supply. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	
	C8635		Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
	C8636		Severe active rheumatoid arthritis Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8637		Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.	Compliance with Written Authority Required procedures

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 of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C8638		Severe active rheumatoid arthritis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
	C8709		Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) a completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
	C9380		Severe active juvenile idiopathic arthritis Continuing Treatment - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C9384		Severe active juvenile idiopathic arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
	C9386		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
	C9407		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application.	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9417		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C9494		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9495		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C9496		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months 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.	Compliance with Written 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. 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 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. 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	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			repeats will be authorised. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C10532		Systemic juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months) Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must be under 18 years of age. 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;	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks 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 month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.	
	C10535		Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; 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 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; 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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 of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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. The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. 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	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(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. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.	
	C10536		Systemic juvenile idiopathic arthritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. 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	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(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 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 4 weeks 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 month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C10541		Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) Must be treated by a paediatric rheumatologist; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10542		Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
	C10545		Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			subsidised biological medicine for this condition; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count must be no more than 4 weeks old at the time of this application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C10567		Systemic juvenile idiopathic arthritis Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND 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. 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. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(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. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C10570		Systemic juvenile idiopathic arthritis Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	
	C10571		Systemic juvenile idiopathic arthritis Balance of supply - Continuing treatment Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with Authority Required procedures
	C10616		Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of 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. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
Ustekinumab	C9655		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR	Compliance with Written 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)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9656		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9710		Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Applications for authorisation must be made in writing and must include: (a) two completed authority prescription forms; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats. A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised. Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
Valaciclovir	C5975		Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 5975
	C9267		Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9267
Valganciclovir	C4980		Cytomegalovirus retinitis Patient must have HIV infection.	Compliance with Authority Required procedures - Streamlined Authority Code 4980
	C4989		Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 4989
	C9316		Cytomegalovirus infection and disease Prophylaxis Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 9316
Vedolizumab	C9682		Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)];	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Department of Human Services website.	
	C9683		Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			vials, to provide for a single infusion of 300 mg per dose. Up to a maximum of 2 repeats will be authorised. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9708		Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Applications for authorisation must be made in writing and must include: (a) 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. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Department of Human Services website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
	C9738		Moderate to severe ulcerative colitis Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)];	Compliance with Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.	
	C9739		Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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. Application for authorisation must be made in writing and must include: (a) a completed authority prescription form; and	Compliance with Written Authority Required procedures

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 if relevant; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 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. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.	
	C9771		Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.	Compliance with Authority Required procedures
	C9792		Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Application for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			TGA-approved Product Information, details must be provided at the time of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. Details of the accepted toxicities including severity can be found on the Department of Human Services website.	
	C9796		Severe Crohn disease Continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must be aged 18 years or older. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by 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.	Compliance with Written Authority Required procedures

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 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. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.	
	C9815		Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.	Compliance with Written 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 biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
	C9825		Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR	Compliance with Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; OR Patient must be assessed clinically as being in a high faecal output state; OR Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			(iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. 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. The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
Zidovudine	C4454		HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents	Compliance with Authority Required procedures - Streamlined Authority Code 4454
	C4512		HIV infection Initial	Compliance with Authority Required

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			Patient must be antiretroviral treatment naïve; AND The treatment must be in combination with other antiretroviral agents	procedures - Streamlined Authority Code 4512
Zoledronic acid	C5605		Bone metastases The condition must be due to breast cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5605
	C5703		Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 5703
	C5704		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 5704
	C5735		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 5735
	C9268		Multiple myeloma	Compliance with Authority Required procedures - Streamlined Authority Code 9268
	C9304		Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Authority Required procedures - Streamlined Authority Code 9304
	C9317		Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9317
	C9328		Bone metastases	Compliance with Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			The condition must be due to breast cancer.	Required procedures - Streamlined Authority Code 9328

Clause 1

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 has been assessed in accordance with paragraph 2 of this Part; and

(2) the patient is:

- (a) treated by a medical practitioner or an authorised nurse practitioner who is experienced in the treatment of patients with chronic hepatitis C infection; or
- (b) treated by a medical practitioner or an authorised nurse practitioner in consultation with:
  - (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) where possible, 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) whether the patient is:
  - (i) cirrhotic; or
  - (ii) non-cirrhotic
- (b) details of the previous treatment regimen (**only** for requests for sofosbuvir with velpatasvir and voxilaprevir or glecaprevir with pibrentasvir for 16 weeks' treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

(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.

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) all genotypes (pan-genotypic); and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) GLECAPREVIR with PIBRENTASVIR for 8 weeks.
2	Patient: (a) all genotypes (pan-genotypic); and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 8 weeks; or (d) GLECAPREVIR with PIBRENTASVIR for 12 weeks; or (e) GLECAPREVIR with PIBRENTASVIR 16 weeks.
3	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) GRAZOPREVIR with ELBASVIR for 12 weeks.
4	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) GRAZOPREVIR with ELBASVIR for 12 weeks; or (c) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks.

Clause 3

Item	Kind of patient	Regimen
5	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
6	Patient: (a) with Genotype 2; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).
7	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
8	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).
9	Patient: (a) with Genotype 4; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	GRAZOPREVIR with ELBASVIR for 12 weeks.
10	Patient: (a) with Genotype 4; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	Either: (a) GRAZOPREVIR with ELBASVIR for 12 weeks; or (b) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks.
11	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment naïve; and (c) who is non-cirrhotic.	Refer to item 1 above (pan-genotypic, treatment naïve and non-cirrhotic regimens).
12	Patient: (a) with:	Refer to item 2 above (pan-genotypic, treatment experienced and non-cirrhotic regimens).

Item	Kind of patient	Regimen
	(i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment experienced; and (c) who is non-cirrhotic.	
13	Patient: (a) all genotypes (pan-genotypic); and (b) who is treatment naïve; and (c) who is cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) GLECAPREVIR with PIBRENTASVIR for 12 weeks.
14	Patient: (a) all genotypes (pan-genotypic); and (b) who is treatment experienced; and (c) who is cirrhotic.	Either: (a) SOFOSBUVIR with VELPATASVIR for 12 weeks; or (b) SOFOSBUVIR with VELPATASVIR and VOXILAPREVIR for 12 weeks; or (c) GLECAPREVIR with PIBRENTASVIR for 12 weeks; or (d) GLECAPREVIR with PIBRENTASVIR 16 weeks.
15	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) GRAZOPREVIR with ELBASVIR for 12 weeks.
16	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) GRAZOPREVIR with ELBASVIR for 12 weeks; or (c) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks.
17	Patient: (a) with Genotype 2; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
18	Patient: (a) with Genotype 2; and (b) who is treatment experienced;	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).

Clause 3

Item	Kind of patient	Regimen
	and (c) who is cirrhotic.	
19	Patient: (a) with Genotype 3; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
20	Patient: (a) with Genotype 3; and (b) who is treatment experienced; and (c) who is cirrhotic.	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).
21	Patient: (a) with Genotype 4; and (b) who is treatment naïve; and (c) who is cirrhotic.	GRAZOPREVIR with ELBASVIR for 12 weeks.
22	Patient: (a) with Genotype 4; and (b) who is treatment experienced; and (c) who is cirrhotic.	Either: (a) GRAZOPREVIR with ELBASVIR for 12 weeks; or (b) GRAZOPREVIR with ELBASVIR and RIBAVIRIN for 16 weeks.
23	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment naïve; and (c) who is cirrhotic.	Refer to item 13 above (pan-genotypic, treatment naïve and cirrhotic regimens).
24	Patient: (a) with: (i) Genotype 5; or (ii) Genotype 6; and (b) who is treatment experienced; and (c) who is cirrhotic.	Refer to item 14 above (pan-genotypic, treatment experienced and cirrhotic regimens).

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 $
Lamivudine	Tablet 100 mg	Oral	Zeffix	28	$34.70	$35.30
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valtrex	100	$44.20	$44.64

Schedule 5—HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic

Note: See section 9AA.

Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic

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

Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic		
Listed drug	**Form**	**Manner of administration**
Infliximab	Powder for I.V. infusion 100 mg	Injection
Ivacaftor	Sachet containing granules 50 mg	Oral
Ivacaftor	Sachet containing granules 75 mg	Oral
Ivacaftor	Tablet 150 mg	Oral
Lenalidomide	Capsule 5 mg	Oral
Lenalidomide	Capsule 10 mg	Oral
Lenalidomide	Capsule 15 mg	Oral
Lenalidomide	Capsule 25 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral
Macitentan	Tablet 10 mg	Oral
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth
Mepolizumab	Powder for injection 100 mg	Injection
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen	Injection
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection
Pomalidomide	Capsule 3 mg	Oral
Pomalidomide	Capsule 4 mg	Oral
Riociguat	Tablet 500 micrograms	Oral
Riociguat	Tablet 1 mg	Oral
Riociguat	Tablet 1.5 mg	Oral
Riociguat	Tablet 2 mg	Oral
Riociguat	Tablet 2.5 mg	Oral
Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection

Schedule 5 HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic

Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic		
Listed drug	**Form**	**Manner of administration**
Sildenafil	Tablet 20 mg (as citrate)	Oral
Tadalafil	Tablet 20 mg	Oral
Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection
Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection
Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection
Vedolizumab	Powder for injection 300 mg	Injection

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)	—
PB 67 of 2016	28 July 2016 (F2016L01240)	1 Aug 2016 (s 2)	—
PB 76 of 2016	30 Aug 2016 (F2016L01365)	1 Sept 2016 (s 2)	—
PB 84 of 2016	30 Sept 2016 (F2016L01559)	1 Oct 2016 (s 2)	—
PB 93 of 2016	31 Oct 2016 (F2016L01664)	1 Nov 2016 (s 2)	—
PB 100 of 2016	30 Nov 2016 (F2016L01842)	1 Dec 2016 (s 2)	—
PB 113 of 2016	22 Dec 2016 (F2016L02027)	1 Jan 2017 (s 2)	—
PB 5 of 2017	25 Jan 2017 (F2017L00066)	1 Feb 2017 (s 2)	—
PB 20 of 2017	31 Mar 2017 (F2017L00378)	1 Apr 2017 (s 2)	—
PB 30 of 2017	28 Apr 2017 (F2017L00489)	1 May 2017 (s 2)	—
PB 39 of 2017	31 May 2017 (F2017L00634)	1 June 2017 (s 2)	—
PB 47 of 2017	30 June 2017 (F2017L00856)	1 July 2017 (s 2)	—
PB 57 of 2017	27 July 2017 (F2017L00959)	1 Aug 2017 (s 2)	—
PB 66 of 2017	31 Aug 2017 (F2017L01117)	1 Sept 2017 (s 2)	—
PB 75 of 2017	26 Sept 2017 (F2017L01271)	1 Oct 2017 (s 2)	—
PB 88 of 2017	30 Oct 2017 (F2017L01399)	1 Nov 2017 (s 2)	—
PB 95 of 2017	1 Dec 2017 (F2017L01555)	1 Dec 2017 (s 2)	—
PB 104 of 2017	15 Dec 2017 (F2017L01626)	1 Jan 2018 (s 2)	—
PB 6 of 2018	30 Jan 2018 (F2018L00068)	1 Feb 2018 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 16 of 2018	28 Feb 2018 (F2018L00162)	1 Mar 2018 (s 2)	—
PB 22 of 2018	28 Mar 2018 (F2018L00428)	1 Apr 2018 (s 2)	—
PB 40 of 2018	1 June 2018 (F2018L00704)	1 June 2018 (s 2)	—
PB 54 of 2018	29 June 2018 (F2018L00951)	1 July 2018 (s 2)	—
PB 67 of 2018	31 July 2018 (F2018L01069)	1 Aug 2018 (s 2)	—
PB 77 of 2018	30 Aug 2018 (F2018L01211)	1 Sept 2018 (s 2)	—
PB 85 of 2018	27 Sept 2018 (F2018L01361)	1 Oct 2018 (s 2)	—
PB 94 of 2018	30 Oct 2018 (F2018L01508)	1 Nov 2018 (s 2)	—
PB 102 of 2018	30 Nov 2018 (F2018L01646)	1 Dec 2018 (s 2)	—
PB 107 of 2018	6 Dec 2018 (F2018L01673)	21 Dec 2018 (s 2(1) item 1)	Sch 2
PB 111 of 2018	20 Dec 2018 (F2018L01814)	1 Jan 2019 (s 2)	—
PB 3 of 2019	31 Jan 2019 (F2019L00081)	1 Feb 2019 (s 2)	—
PB 13 of 2019	28 Feb 2019 (F2019L00216)	1 Mar 2019 (s 2)	—
PB 20 of 2019	29 Mar 2019 (F2019L00459)	1 Apr 2019 (s 2)	—
PB 31 of 2019	30 Apr 2019 (F2019L00661)	1 May 2019 (s 2)	—
PB 39 of 2019	30 May 2019 (F2019L00697)	1 June 2019 (s 2)	—
PB 48 of 2019	28 June 2019 (F2019L00919)	1 July 2019 (s 2)	—
PB 61 of 2019	31 July 2019 (F2019L01023)	1 Aug 2019 (s 2)	—
PB 70 of 2019	30 Aug 2019 (F2019L01123)	1 Sept 2019 (s 2)	—
PB 78 of 2019	30 Sept 2019 (F2019L01295)	1 Oct 2019 (s 2)	—

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 87 of 2019	31 Oct 2019 (F2019L01395)	1 Nov 2019 (s 2)	—
PB 95 of 2019	28 Nov 2019 (F2019L01518)	1 Dec 2019 (s 2)	—
PB 106 of 2019	23 Dec 2019 (F2019L01688)	1 Jan 2020 (s 2)	—
PB 4 of 2020	31 Jan 2020 (F2020L00080)	1 Feb 2020 (s 2)	—
PB 17 of 2020	28 Feb 2020 (F2020L00185)	1 Mar 2020 (s 2)	—
PB 24 of 2020	31 Mar 2020 (F2020L00356)	1 Apr 2020 (s 2)	—
PB 26 of 2020	31 Mar 2020 (F2020L00366)	1 Apr 2020 (s 2(1) item 1)	—
PB 32 of 2020	30 Apr 2020 (F2020L00531)	Sch 1 (items 4–6): 1 May 2020 (s 2(1) item 1)	—
PB 37 of 2020	30 Apr 2020 (F2020L00538)	1 May 2020 (s 2)	—
PB 46 of 2020	29 May 2020 (F2020L00646)	1 June 2020 (s 2)	—
PB 72 of 2020	31 July 2020 (F2020L00971)	1 Aug 2020 (s 2)	—
PB 82 of 2020	28 Aug 2020 (F2020L01090)	1 Sept 2020 (s 2)	—
PB 100 of 2020	29 Sept 2020 (F2020L01247)	Sch 1 (item 3):30 Sept 2020 (s 2(1) item 1)	—
PB 93 of 2020	30 Sept 2020 (F2020L01267)	1 Oct 2020 (s 2)	—
PB 109 of 2020	30 Oct 2020 (F2020L01366)	Sch 1 (item 6): 1 Nov 2020 (s 2(1) item 3)	—
PB 106 of 2020	30 Oct 2020 (F2020L01368)	1 Nov 2020 (s 2)	—

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
Division 1	
s 1	am PB 58 of 2015
s 2	rep LA s 48D
s 3	rep LA s 48C
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 (Sch 1 item 1 md); PB 33, 67, 76, 84 and 113 of 2016; PB 30 of 2017; PB 66 of 2017; PB 75 of 2017; PB 104 of 2017; PB 40 of 2018
	ed C82
	am PB 85 of 2018; PB 102 of 2018; PB 107 of 2018; PB 3 of 2019; PB 13 of 2019; PB 78 of 2019; PB 95 of 2019; PB 17 of 2020; PB 24 of 2020; PB 26 of 2020
	ed C105
	am PB 46 of 2020
s 4A	ad PB 26 of 2020
	am PB 93 of 2020; PB 106 of 2020
	ed C112
Division 2	
s 7	am PB 87 of 2019
s 8	am PB 26 of 2020; PB 109 of 2020
s 9	am PB 32 of 2020
	(3) rep 1 Apr 2021 (s 9AA(3))
s 9AA	ad PB 32 of 2020
	am PB 100 of 2020
	rep 1 Apr 2021 (s 9AA(3))
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
Division 4	
s 14	am PB 87 of 2019; PB 26 of 2020

Endnote 4—Amendment history

Provision affected	How affected
s 15	am PB 26 of 2020
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 of 2015; PB 58 of 2015
	rs PB 107 of 2018
s 20	am PB 26 of 2020
Division 3	
s 21	am PB 30 of 2015; PB 107 of 2018; PB 26 of 2020
s 22	rep PB 30 of 2015
s 22A	ad PB 93 of 2014
	am PB 26 of 2020
Division 4	
s 23	am PB 30 of 2015; PB 107 of 2018; PB 26 of 2020
s 23A	ad PB 93 of 2014
	am PB 26 of 2020
s 24	am PB 2, 28, 46 and 99 of 2011; PB 5, 20 and 31 of 2012
	rs PB 63 of 2013
	am PB 113 of 2016; PB 5 of 2017; PB 66 of 2017
	ed C74
	am PB 75 of 2017; PB 88 of 2017; PB 40 of 2018; PB 26 of 2020
s 25	am PB 2, 28, 46 and 99 of 2011; PB 20 and 31 of 2012
	rs PB 63 of 2013
	am PB 113 of 2016; PB 5 of 2017; PB 66 of 2017
	ed C74
	am PB 75 of 2017; PB 88 of 2017; PB 40 of 2018
	ed C82
	am PB 26 of 2020
s 26	rs PB 30 of 2015; PB 107 of 2018
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

Provision affected	How affected
s 29	rep PB 30 of 2015
Division 2	
Subdivision 1	
s 30	am PB 30 of 2015; PB 87 of 2019
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; PB 104 of 2017; PB 4 of 2020
s 40	am PB 76 and 96 of 2012
s 41	rs PB 76 of 2012
s 42	rs PB 26 of 2020
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
	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; PB 107 of 2018; PB 87 of 2019

Endnote 4—Amendment history

Provision affected	How affected
Part 8	
s 52	am PB 62 of 2011; PB 107 of 2018
Part 9	
s 54	rep PB 30 of 2015
	ad PB 30 of 2015
	am PB 107 of 2018
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 and 63 of 2014; PB 93 of 2014 (Sch 1 items 13, 14 md); PB 102 of 2014; PB 3, 30, 43, 50, 58, 72, 83, 94, 104, 111, 121 and 129 of 2015; PB 5 and 13 of 2016; PB 22 of 2016 (Sch 1 items 1–3, 6 md); PB 33, 45, 55, 67 and 76 of 2016; PB 84 of 2016 (Sch 1 item 8 md); PB 93, 100 and 113 of 2016; PB 5 of 2017; PB 20 of 2017; PB 30 of 2017; PB 39 of 2017; PB 47 of 2017; PB 57 of 2017; PB 66 of 2017; PB 75 of 2017; PB 88 of 2017; PB 95 of 2017; PB 104 of 2017; PB 6 of 2018; PB 16 of 2018; PB 22 of 2018; PB 40 of 2018
	ed C82
	am PB 54 of 2018; PB 67 of 2018
	ed C84
	am PB 77 of 2018
	ed C85
	am PB 85 of 2018; PB 94 of 2018; PB 102 of 2018; PB 111 of 2018; PB 3 of 2019; PB 13 of 2019; PB 20 of 2019; PB 31 of 2019; PB 39 of 2019; PB 48 of 2019; PB 61 of 2019; PB 70 of 2019; PB 78 of 2019
	ed C99
	am PB 87 of 2019; PB 95 of 2019; PB 106 of 2019; PB 4 of 2020; PB 17 of 2020; PB 24 of 2020; PB 26 of 2020; PB 37 of 2020; PB 46 of 2020; PB 72 of 2020; PB 82 of 2020; PB 93 of 2020; PB 106 of 2020
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, 22, 67, 93 and 113 of 2016; PB 20 of 2017
	rs PB 104 of 2017
	am PB 16 of 2018; PB 22 of 2018; PB 40 of 2018; PB 85 of 2018; PB 94 of 2018; PB 102 of 2018; PB 111 of 2018; PB 3 of 2019; PB 31 of 2019; PB 61 of 2019; PB 87 of 2019; PB 95 of 2019; PB 4 of 2020; PB 24 of 2020; PB 37 of 2020; PB 72 of 2020; PB 82 of 2020; PB 106 of 2020

Provision affected	How affected
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 and 63 of 2014; PB 93 of 2014 (Sch 1 item 24 md); PB 3, 30, 43, 50, 58, 72, 83, 94, 104, 111, 121 and 129 of 2015; PB 5, 13, 22, 33, 45, 55, 67, 76, 84, 93, 100 and 113 of 2016; PB 5 of 2017; PB 30 of 2017; PB 39 of 2017; PB 47 of 2017; PB 57 of 2017; PB 66 of 2017; PB 75 of 2017; PB 88 of 2017; PB 95 of 2017; PB 104 of 2017; PB 6 of 2018; PB 16 of 2018; PB 22 of 2018; PB 40 of 2018
	ed C82
	am PB 54 of 2018; PB 67 of 2018; PB 77 of 2018; PB 85 of 2018; PB 94 of 2018; PB 102 of 2018; PB 111 of 2018; PB 3 of 2019; PB 13 of 2019; PB 20 of 2019; PB 31 of 2019; PB 48 of 2019
	ed C96
	am PB 61 of 2019; PB 70 of 2019; PB 78 of 2019 (Sch 1 par 46(a) md not incorp)
	ed C99
	am PB 87 of 2019; PB 95 of 2019; PB 106 of 2019; PB 4 of 2020; PB 17 of 2020; PB 24 of 2020; PB 37 of 2020
	ed C106
	am PB 46 of 2020; PB 72 of 2020; PB 82 of 2020; PB 93 of 2020; PB 106 of 2020
Part 1	
Part 1	rs PB 24 of 2020; PB 106 of 2020
c 1	ad PB 13 of 2016
	rs PB 113 of 2016; PB 39 of 2017; PB 24 of 2020; PB 106 of 2020
c 2	ad PB 13 of 2016
	rs PB 113 of 2016; PB 24 of 2020; PB 106 of 2020
c 3	ad PB 13 of 2016
	rs PB 113 of 2016
	am PB 5 of 2017; PB 66 of 2017; PB 75 of 2017; PB 77 of 2018
	ed C85
	am PB 3 of 2019
	ed C91
	am PB 20 of 2019
	rs PB 24 of 2020; PB 106 of 2020
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; PB 84 and 100 of 2016; PB 20 of 2017; PB 75 of 2017
Schedule 5	
Schedule 5	ad PB 32 of 2020
	am PB 46 of 2020

Endnote 4—Amendment history

Provision affected	How affected
	rep 1 Apr 2021 (s 9AA(3))

Endnote 5—Editorial changes

In preparing this compilation for registration, the following kinds of editorial change(s) were made under the *Legislation Act 2003*.

Subsection 4A(2)

Kind of editorial change

Removal of redundant text and changes to punctuation

Details of editorial change

Schedule 1 item 1 of the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 9)* (PB 106 of 2020) instructs to omit "(d) sofosbuvir" from subsection 4A(2).

This amendment does not include the full stop at the end of paragraph 4A(2)(d).

This compilation was editorially changed to omit the redundant full stop.

This amendment results in paragraph 4A(2)(b) ending with a semicolon and paragraph 4A(2)(c) ending with "; and" despite now being the last paragraph of that subsection.

This compilation was also editorially changed to insert "and" at the end of paragraph 4A(2)(b) and replace "; and" at the end of paragraph 4A(2)(c) with a full stop to bring it into line with legislative drafting practice.