PB 116 of 2010

National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010[1]

National Health Act 1953

I, DAVID LEARMONTH, Deputy Secretary, Department of Health and Ageing, make this Special Arrangement under subsections 100 (1) and (2) of the *National Health Act 1953*.

Dated 28 November 2010

Signed by D Learmonth

Deputy Secretary,
Department of Health and Ageing

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Part 1 Preliminary

Division 1 General

1 Name of Special Arrangement

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

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

2 Commencement

This Special Arrangement commences on 1 December 2010.

3 Revocation

The following Instruments are revoked:

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

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

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

4 Definitions

In this Special Arrangement:

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

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

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

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.

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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 Medicare Australia CEO 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 public hospital means a public hospital that has an approved hospital authority.

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

benefit card means any of the following:

(a) a PBS Entitlement Card;

(b) a PBS Safety Net Concession Card;

(c) a Pensioner Concession Card;

(d) a Health Care Card (including Low Income Health Care Card and Foster Child Health Care Card);

(e) a Commonwealth Seniors Health Card;

(f) a Cleft Lip and Palate Card;

(g) a DVA Gold Card;

(h) a DVA White Card;

(i) a DVA Orange Card;

(j) War Widow/Widower Transport Card;

(k) a card or voucher approved by the Medicare Australia CEO for this paragraph.

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

(a) abatacept;

(b) adalimumab;

(c) ambrisentan;

(d) bosentan;

(e) epoprostenol;

(f) etanercept;

(g) iloprost;

(h) infliximab;

(i) lenalidomide;

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(j) rituximab;
(k) sildenafil;
(l) sitaxentan;
(m) tocilizumab.

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

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

dispensed price:

(a) for the supply of an HSD pharmaceutical benefit by a hospital authority for a public hospital — has the meaning given by section 37; and

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

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

(a) who is an affiliated specialist medical practitioner; or

(b) who is, for the prescription of medication for the treatment of HIV or AIDS — an accredited prescriber of medication for the treatment of HIV or AIDS; or

(c) who is, for the prescription of medication for the treatment of Hepatitis C — an accredited prescriber of medication for the treatment of Hepatitis C; 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) is receiving medical treatment by a medical practitioner at, or from, a hospital as:

(i) a non-admitted patient; or

(ii) a day admitted patient; or

(iii) a patient on discharge.

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

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.

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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.

manufacturers' pack, for an HSD pharmaceutical benefit, has the same meaning as in subsection 6 (2) of the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, as in force from time to time.

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

(a) abacavir;

(b) abacavir with lamivudine;

(c) abacavir with lamivudine and zidovudine;

(d) atazanavir;

(e) azithromycin;

(f) cidofovir;

(g) clarithromycin;

(h) darunavir;

(i) didanosine;

(j) doxorubicin, pegylated liposomal;

(k) efavirenz;

(l) emtricitabine;

(m) enfuvirtide;

(n) etravirine;

(o) fosamprenavir;

(p) foscarnet;

(q) ganciclovir;

(r) indinavir;

(s) lamivudine;

(t) lamivudine with zidovudine;

(u) lopinavir with ritonavir;

(v) maraviroc;

(w) nevirapine;

(x) raltegravir;

(y) rifabutin;

(z) ritonavir;

(za) saquinavir;

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(zb) stavudine;
(zc) tenofovir;
(zd) tenofovir with emtricitabine;
(ze) tenofovir with emtricitabine and efavirenz;
(zf) valaciclovir;
(zg) valganciclovir;
(zh) zidovudine.

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

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

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

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

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

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

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 pharmacist
- hospital
- medical practitioner
- Medicare Australia CEO
- pharmaceutical benefit
- pharmaceutical item
- private hospital
- public hospital.

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.

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6 Application of Part VII of the Act

(1) Each HSD pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act.

(2) A provision of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act, applies subject to this Special Arrangement.

Note See subsection 100 (3) of the Act.

7 Responsible person

(1) If a code is mentioned in the column in Schedule 1 headed 'Responsible Person' for a brand of a pharmaceutical item, the person mentioned in paragraph (2) (a) is the responsible person for the brand of the pharmaceutical item.

(2) For subsection (1):

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

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

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

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

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

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

8 Authorised Prescriber

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

(2) For this Special Arrangement:

(a) only an eligible medical practitioner is an authorised prescriber; and

(b) the ***prescriber code*** for the authorised prescriber is the letters 'EMP'.

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

(4) For subsection (1), the HSD pharmaceutical benefit is the brand of the listed drug mentioned in Schedule 1:

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

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

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

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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.

Division 3 HSD modified Authority Required procedures

Note: This Division modifies in some cases the Authority Required Procedures that are set out in the National Health (Listing of Pharmaceutical Benefits) Instrument 2010.

10 HSD modified 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 Written or Telephone Authority Required procedures; or

(b) Compliance with modified Authority Required procedures.

(2) A prescription for the supply of the HSD pharmaceutical benefit must be:

(a) submitted by the eligible medical practitioner to the Medicare Australia CEO in accordance with section 11; and

(b) authorised by the Medicare Australia CEO in accordance with section 12.

11 HSD modified Authority Required procedures — submission of prescription

(1) The eligible medical practitioner must:

(a) deliver or post to the Medicare Australia CEO a prescription for the supply of the HSD pharmaceutical benefit, prepared and signed by the eligible medical practitioner:

(i) in a form approved by the Secretary and completed by the eligible medical practitioner in ink in his or her own handwriting; or

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(ii) in a form, prepared by means of a computer, that is in accordance with the form approved by the Secretary under subparagraph (i); or

(iii) in a form, prepared by means of a computer, approved in writing for the purpose by the Secretary and in the format approved in writing by the Secretary; or

(iv) by a method approved in writing by the Secretary; or

(b) submit to the Medicare Australia CEO, by telephone, details of a prescription for the supply of the HSD pharmaceutical benefit prepared and signed by the eligible medical practitioner in accordance with subparagraph (a) (i), (ii), (iii) or (iv); or

(c) if the eligible medical practitioner has attempted to give details of the prescription to the Medicare Australia CEO in accordance with paragraph (b) but has been unable to do so because the telephone system established by the Medicare Australia CEO for the provision of such authorisations was unavailable — submit the prescription in accordance with the instructions in an emergency telephone message provided to the eligible medical practitioner by the Medicare Australia CEO.

(2) If a circumstance mentioned in Schedule 3 for a circumstances code applying to the HSD pharmaceutical benefit includes Compliance with Written or Telephone Authority Required procedures, the eligible medical practitioner must submit a prescription for the supply of the HSD pharmaceutical benefit to the Medicare Australia CEO in accordance with paragraph (1) (a), (b) or (c).

(3) If a circumstance mentioned in Schedule 3 for a circumstances code applying to the HSD pharmaceutical benefit includes Compliance with modified Authority Required procedures, the eligible medical practitioner must:

(a) for circumstances that require the authority application to be submitted in writing – submit a prescription for the supply of the HSD pharmaceutical benefit to the Medicare Australia CEO in accordance with:

(i) paragraph 1(a); and

(ii) any other requirements included in the circumstance;

(b) for circumstances that require the authority application to be submitted by telephone – submit a prescription for the supply of the HSD pharmaceutical benefit to the Medicare Australia CEO in accordance with:

(i) paragraph 1(b) or (c); and

(ii) any other requirements included in the circumstance;

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(c) for circumstances that allow the authority application to be submitted by telephone – submit a prescription for the supply of the HSD pharmaceutical benefit to the Medicare Australia CEO in accordance with:

(i) paragraph 1(a), (b) or (c); and

(ii) any other requirements included in the circumstance.

(4) For paragraph (1) (a), a prescription prepared and signed by the eligible medical practitioner in accordance with subsection (1) is taken to have been submitted by the eligible medical practitioner if it is submitted by his or her employee.

12 HSD modified Authority Required procedures — authorisation

(1) A prescription submitted in accordance with paragraph 11 (1) (a) may be authorised by the Medicare Australia CEO:

(a) signing his or her authorisation on the prescription; and

(b) either:

(i) if the Medicare Australia CEO requires the eligible medical practitioner to alter the prescription — returning it to the eligible medical practitioner for alteration before the eligible medical practitioner gives it to the person in respect of whom it was prepared; or

(ii) in any other case:

(A) returning the authorised prescription to the eligible medical practitioner; or

(B) sending it to the person in respect of whom it was prepared.

(2) A prescription submitted in accordance with paragraph 11 (1) (b) may be authorised by the Medicare Australia CEO telling the eligible medical practitioner by telephone, at the time the Medicare Australia CEO is given details of the prescription, that the prescription is authorised.

(3) If the Medicare Australia CEO authorises a prescription under subsection (2):

(a) the Medicare Australia CEO must tell the eligible medical practitioner the number given by the CEO to the prescription: and

(b) the eligible medical practitioner must:

(i) mark that number on the prescription; and

(ii) retain a copy of the prescription for 1 year from the date the prescription was authorised.

(4) For paragraph (3) (a), the Medicare Australia CEO must tell the eligible medical practitioner the number by telephone or by electronic communication.

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(5) A prescription submitted in accordance with paragraph 11 (1) (c) is taken to have been authorised by the Medicare Australia CEO if the eligible medical practitioner completes the prescription in accordance with the instructions given in the emergency telephone message.

13 HSD modified Streamlined authority code

(1) This section applies to an HSD pharmaceutical benefit if the circumstances mentioned in Schedule 3 for a circumstances code applying to the HSD pharmaceutical benefit include the words 'Streamlined Authority Code' followed by a number.

(2) The requirements of section 11 are taken to have been complied with, and the Medicare Australia CEO is taken to have authorised the prescription of the HSD pharmaceutical benefit under section 12, if the eligible medical practitioner has:

(a) prepared and signed a prescription for the supply of the HSD pharmaceutical benefit in accordance with subparagraph 11 (1) (a) (i), (ii), (iii) or (iv) and written the Streamlined Authority Code on the prescription; or

(b) if the eligible medical practitioner is at a public hospital — prepared a medication chart for the HSD pharmaceutical benefit in accordance with section 22 and written the Streamlined Authority Code on the medication chart.

Division 4 Maximum quantity and maximum number of repeats

14 Maximum quantity

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

(2) If at least 1 purposes code is mentioned in the column in Schedule 1 headed 'Purposes' for an HSD pharmaceutical benefit, the quantity or number of units mentioned in the column headed 'Maximum Quantity' is the maximum for the particular purposes mentioned in Schedule 3 for each code.

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

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

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

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

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

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

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

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

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

Note 2 See also section 26.

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

15 Maximum number of repeats

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

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

(3) If no purposes code is mentioned in the column headed 'Purposes', the number of repeats mentioned in the column headed 'Number of Repeats' is the maximum number for all purposes, other than a purpose for which a different maximum is mentioned for the same pharmaceutical benefit.

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

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

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

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

Note See also section 26.

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

Division 5 Section 100 only

16 Section 100 only supply

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

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

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

(3) If the letters 'PB' are mentioned in the column in Schedule 1 headed 'Section 100 only' for an HSD pharmaceutical benefit, the HSD pharmaceutical benefit may be supplied only in accordance with this Special Arrangement and any other Special Arrangement relating to the pharmaceutical benefit.

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

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

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

(6) An HSD pharmaceutical benefit mentioned in subsection (5) is not available in the circumstances mentioned in subsection (5) for general supply on the Pharmaceutical Benefits Scheme.

Note The Minister has determined, under paragraph 85 (8) (b) of the Act, that 1 or more of the circumstances in which a prescription for the supply of the HSD pharmaceutical benefit may be written are circumstances in which the benefit can only be supplied under a section 100 Special Arrangement.

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Part 2 Supply of HSD pharmaceutical benefits

Division 1 General requirements for supply

17 Entitlement to HSD pharmaceutical benefits

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

18 Supply of HSD pharmaceutical benefits under this Special Arrangement

(1) This Special Arrangement only applies to the supply of an HSD pharmaceutical benefit:

(a) by an approved hospital authority for a hospital to an eligible patient receiving treatment at or from the hospital; or

(b) by a hospital authority for a public hospital to an eligible patient receiving treatment at or from the 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 a public hospital.

(2) Subsection (1) does not require a hospital authority or an approved pharmacist to supply the HSD pharmaceutical benefit directly to a patient.

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

Division 2 Repeat prescriptions

19 Application of regulation 25

Regulation 25 of the Regulations:

(a) does not apply to the supply of an HSD pharmaceutical benefit under this Special Arrangement to an eligible patient receiving treatment at or from a public hospital; and

(b) applies to the supply of an HSD pharmaceutical benefit under this Special Arrangement to an eligible patient receiving treatment at or from a private hospital as if the HSD pharmaceutical benefit were a pharmaceutical benefit in relation to which the Minister has determined, under paragraph 85A (2) (b) of the Act, that the maximum number of occasions on which the supply of the benefit may, in one prescription be directed to be repeated is more than 4.

Note Regulation 25 provides that a pharmaceutical benefit must not be supplied on more occasions than the prescription provides, unless the pharmaceutical benefit has a maximum number of repeats of more than 4 determined under paragraph 85A (2) (b) of the Act. In that case, and in certain circumstances, a person may be again supplied the pharmaceutical benefit, or another brand of the pharmaceutical benefit, despite receiving a supply in the previous 20 days.

20 No repeats for visitors

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

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

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

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

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

(b) if the eligible medical practitioner is at a public hospital — preparing a medication chart for the HSD pharmaceutical benefit in accordance with section 22.

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

22 Information to be included in medication chart

(1) For paragraph 21 (b), a medication chart for an eligible patient must include the following information:

(a) the name and provider number of the hospital where the chart is prepared;

(b) the name, signature and prescriber number of the eligible medical practitioner;

(c) the streamlined authority code for the HSD pharmaceutical benefit, if applicable;

(d) the patient's name and address;

(e) the patient's entitlement number, if applicable;

(f) the letters 'PBS' or 'RPBS', as appropriate;

(g) the following details about the HSD pharmaceutical benefit:

(i) the name of the drug;

(ii) the strength of the drug;

(iii) the quantity or dosage of the HSD pharmaceutical benefit or both the quantity and dosage of the HSD pharmaceutical benefit;

(iv) if the dosage of the HSD pharmaceutical benefit is provided under subparagraph (iii) – how often the HSD pharmaceutical benefit is to be taken by the patient and the period that the HSD pharmaceutical benefit is prescribed;

(v) the number of repeats authorised for the HSD pharmaceutical benefit.

(h) the date the medication chart is prepared.

(2) A medication chart prepared in accordance with subsection (1) is taken to be a duly written prescription for regulation 19 of the Regulations.

Division 4 Prescribing HSD pharmaceutical benefits that have CAR drugs

23 Prescriptions for HSD pharmaceutical benefits that have CAR drugs

An eligible medical practitioner may prescribe an HSD pharmaceutical benefit that has a CAR drug by preparing and signing a prescription for the drug.

24 HSD pharmaceutical benefits that have CAR drugs — quantity exceptions

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

(2) The drugs and limitations are as follows:

(a) for HSD pharmaceutical benefits that have the drug ambrisentan, bosentan, epoprostenol, etanercept, iloprost, sildenafil or sitaxentan — 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;

(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 — 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:

(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.

25 HSD pharmaceutical benefits that have CAR drugs — repeat exceptions

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

(2) The drugs and limitations are as follows:

(a) for bosentan:

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

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

(b) for etanercept:
  (i) for the initial treatment of severe polyarticular course juvenile chronic arthritis — up to 3 repeat supplies; or
  (ii) for the continuing treatment of severe polyarticular course juvenile chronic arthritis — up to 5 repeat supplies;
(c) for infliximab, for the treatment of an adult with severe active rheumatoid arthritis:
  (i) if the circumstances permit a course of up to a maximum of 22 weeks of treatment to be authorised — up to 3 repeat supplies; or
  (ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised — up to 2 repeat supplies;
(d) for infliximab, for the treatment of an adult with severe active psoriatic arthritis:
  (i) if the circumstances permit a course of up to a maximum of 22 weeks of treatment to be authorised — up to 3 repeat supplies; or
  (ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised — up to 2 repeat supplies;
(e) for infliximab, for the treatment of an adult with active ankylosing spondylitis — up to 3 repeat supplies;
(f) for infliximab, for the treatment of a patient with refractory Crohn disease or fistulating Crohn disease — up to 2 repeat supplies;
(g) for infliximab, for the treatment of an adult with severe chronic plaque psoriasis:
  (i) if the circumstances permit a course of up to a maximum of 22 weeks of treatment to be authorised — up to 3 repeat supplies; or
  (ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised — up to 2 repeat supplies;
(h) for abatacept, for the treatment of an adult with severe active rheumatoid arthritis:
  (i) if the circumstances permit a course of up to a maximum of 16 weeks of treatment to be authorised — up to 4 repeat supplies; or
  (ii) if the circumstances permit a course of up to a maximum of 24 weeks of treatment to be authorised — up to 5 repeat supplies;
(i) for rituximab — 1 repeat supply;
(j) for ambrisentan:
  (i) for the initial PBS-subsidised treatment of a patient who was receiving non-PBS-subsidised treatment with ambrisentan for less than 6 months before 1 December 2009 — sufficient repeat supplies to allow the patient to complete a period of combined PBS-subsidised and non-PBS-subsidised therapy of up to 6 months duration in total; or

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

(k) for lenalidomide — up to 2 repeat supplies;

(l) for epoprostenol, iloprost, sildenafil or sitaxentan — up to 5 repeat supplies;

(m) 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;

(n) 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.

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

26 Application of regulation 13 in relation to CAR drugs

Regulation 13 of the Regulations does not apply in relation to an eligible patient for whom a prescription for an HSD pharmaceutical benefit that has a CAR drug is submitted under this Special Arrangement by an eligible medical practitioner.

Part 3 Dispensing requirements

27 How HSD pharmaceutical benefits must be dispensed in certain public hospitals

(1) This section applies if a hospital authority for a public hospital that is not an approved public hospital supplies an HSD pharmaceutical benefit.

(2) The hospital authority for the hospital is eligible for payment under this Special Arrangement only if:

(a) the hospital authority ensures that the HSD pharmaceutical benefit is dispensed by, or under the direct supervision of:

(i) a pharmacist or medical practitioner employed in the public hospital where the HSD pharmaceutical benefit is dispensed; or

(ii) an agent of the public hospital who is a pharmacist or a medical practitioner; and

(b) before dispensing the HSD pharmaceutical benefit, the pharmacist or medical practitioner receives:

(i) a properly completed medication chart, or prescription, under section 21 that, at the time of receipt, is not more that 12 months old and otherwise complies with this Special Arrangement; or

(ii) a prescription under section 23 that, at the time of receipt, is not more than 12 months old and otherwise complies with this Special Arrangement; or

(iii) a repeat authorisation that is:

(A) attached to a prescription mentioned in paragraph (a) or (b); and

(B) received no more than 12 months after date of the original prescription.

Note Approved hospital authorities and approved pharmacists must also ensure that the pharmaceutical benefits they supply are only dispensed by, or under the supervision of, a medical practitioner or a pharmacist — see s103 (3) of the Act.

Part 4 Claiming procedures and payment amounts

Division 1 Off-line claims

28 How off-line claims to be made

(1) Subject to Division 2, if a hospital authority for a public hospital supplies an HSD pharmaceutical benefit under this Special Arrangement, the State or Territory agency responsible for the hospital must make an off-line claim for payment by:

(a) lodging with Medicare Australia 1 claim per calendar month for payment for all HSD pharmaceutical benefits dispensed by all public hospitals making an off-line claim within the State and Territory; and

(b) lodging that claim within 3 months (or such longer period as Medicare Australia allows) after the end of the relevant month in which the HSD pharmaceutical benefits were dispensed; and

(c) including in the claim the following information for each supply of an HSD pharmaceutical benefit:

(i) the month in which the HSD pharmaceutical benefit was dispensed;

(ii) the State or Territory in which the HSD pharmaceutical benefit was dispensed;

(iii) the item code for the HSD pharmaceutical benefit;

(iv) the name of the drug in the HSD pharmaceutical benefit that was dispensed;

(v) the form of the drug in the HSD pharmaceutical benefit that was dispensed;

(vi) the price for which the HSD pharmaceutical benefit was dispensed.

(2) If the HSD pharmaceutical benefit dispensed was an HSD pharmaceutical benefit that has a CAR drug, the claim must also include the following information for each supply of the HSD pharmaceutical benefit:

(a) the hospital provider number of the hospital dispensing the HSD pharmaceutical benefit;

(b) the authority approval number allotted to the prescription by the Medicare Australia CEO;

(c) whether the supply is the original supply or a repeat supply;

(d) the supply date for the HSD pharmaceutical benefit;

(e) the quantity of the HSD pharmaceutical benefit supplied, including the size and number of manufacturers' packs supplied.

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29 Limit of payment

(1) The Government of the State or Territory in which the public hospital is located is entitled to be paid 99.2% of the dispensed price for the supply of the HSD pharmaceutical benefit for which a claim is made under this Division.

(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 2 Modified section 99AAA claims by approved public hospitals

Subdivision 1 General requirements

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

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

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

Note 2 The Rules made by the Minister under subsection 99AAA (8) of the Act allow on-line claims for payment for the supply of a pharmaceutical benefit to be made in certain circumstances.

31 Limit on number of prescriptions in one claim

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

Subdivision 2 Paperless claims for HSD pharmaceutical benefits that have non-CAR drugs

32 Application

(1) A paperless claim for payment for the supply of an HSD pharmaceutical benefit that has a non-CAR drug may be made only:

(a) by an approved hospital authority for a public hospital making an on-line claim; and

(b) for an HSD pharmaceutical benefit that has a non-CAR drug supplied by the hospital authority to an eligible patient under a prescription or medication chart under section 21.

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(2) A paperless claim under this Subdivision may not be made for payment for the supply an HSD pharmaceutical benefit that has a non-CAR drug if the prescription is for more than the maximum quantity, or more than the maximum number of repeats, of the HSD pharmaceutical benefit.

33 Paperless claiming

(1) The approved hospital authority may submit the claim without including a copy of the prescription to which the claim relates only if:

(a) the prescription for the HSD pharmaceutical benefit is written before the HSD pharmaceutical benefit is dispensed; and

(b) the pharmacist, or medical practitioner, who dispenses the HSD pharmaceutical benefit at the hospital:

(i) sights the original prescription before dispensing the HSD pharmaceutical benefit; and

(ii) dispenses the HSD pharmaceutical benefit to an eligible patient.

(2) A claim for an HSD pharmaceutical benefit that has a non-CAR drug must indicate if it is a paperless claim.

34 Records to be kept

(1) If an approved hospital authority makes a paperless claim under this Subdivision, it must keep a paper copy of the prescription or medication chart to which the claim relates.

(2) The copy must be kept for 2 years after the date the HSD pharmaceutical benefit to which the prescription or medication chart relates is dispensed.

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

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 is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the pharmacist's supply of an HSD pharmaceutical benefit is greater than the amount that the approved pharmacist 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 is to be worked out under Division 2 of Part 5.

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

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Part 5 Dispensed price

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

37 The dispensed price — supply by public hospital

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

(a) if the quantity of the HSD pharmaceutical benefit that is ordered and supplied is equal to the quantity contained in the manufacturers' pack — the price ex-manufacturer for the pack;

(b) if the quantity of the HSD pharmaceutical benefit that is ordered and supplied is less than the quantity contained in the manufacturers' pack — 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 the quantity contained in the manufacturers' pack — the sum of:

(i) the price ex-manufacturer for each complete pack contained in the quantity supplied; and

(ii) the amount calculated in accordance with section 38 for the quantity supplied that is less than the quantity contained in the manufacturers' pack.

38 Where quantity is less than in manufacturers' pack

If the quantity of an HSD pharmaceutical benefit that is ordered and supplied is less than the quantity contained in the manufacturers' pack (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 quantity or number of units in the manufacturers' pack, expressed as a percentage to 2 decimal place; and

(b) applying that percentage to the price ex-manufacturer for each complete pack.

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

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

(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, is as follows:

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

(i) the price ex-manufacturer of the manufacturers' pack, 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 *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, 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 *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, 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 the quantity contained in the manufacturers' pack, 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 *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, 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

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fee mentioned in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, 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 the quantity contained in the manufacturers' pack, the sum of:

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

(ii) the amount calculated in accordance with section 41 for that remainder, if any, of the quantity supplied that is less than the quantity contained in the manufacturers' pack, as applicable; and

(iii) either:

(A) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, 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 *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*, 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;

(b) stavudine as a powder for oral solution 1mg per mL, 200 mL;

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

40 Mark-up

For section 39, the mark-up is as follows:

(a) if the price ex-manufacturer for the manufacturers' pack of the HSD pharmaceutical benefit is less than $40.00 — 10% of that price;

(b) if the price ex-manufacturer for the manufacturers' pack of the HSD pharmaceutical benefit is $40.00 or more but not more than $100.00 — $4.00;

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(c) if the price ex-manufacturer for the manufacturers' pack of the HSD pharmaceutical benefit is more than $100.00 but not more than $1 000.00 — 4% of that price;

(d) if the price ex-manufacturer for the manufacturers' pack of the HSD pharmaceutical benefit is more than $1 000.00 — $40.00.

41 Dispensed price if quantity is less than in manufacturers' pack

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

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

(b) working out the percentage of the quantity or number of units in the broken quantity that relates to the quantity or number of units in the manufacturers' pack; and

(c) taking the percentage worked out under paragraph (b) of the amount worked out under subparagraph (a).

42 Dispensing fee

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

Division 3 Dispensed price — other matters

43 Lowest price to be applied

If there are 2 or more HSD pharmaceutical benefits mentioned in Schedule 1 that are different brands but have the same drug in the same form with the same manner of administration, the dispensed price of those HSD pharmaceutical benefits is to be based on the price ex-manufacturer of the HSD pharmaceutical benefit with the lowest dispensed price.

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

45 Patient contributions if off-line claim is made

(1) This section applies if a hospital authority for a public hospital supplies an HSD pharmaceutical benefit to an eligible patient and the State or Territory agency responsible for the hospital makes an off-line claim.

(2) The hospital authority for the hospital may charge the patient:

(a) the relevant amount specified as the maximum value of a supply of out-patient medication in the *Determination made pursuant to subsection* 84BA (2) of the *National Health Act 1953* as in force on the date of the supply of the HSD pharmaceutical benefit; and

(b) an amount mentioned in subsection 48 (1) if the HSD pharmaceutical benefit for supply to the eligible patient is:

(i) a listed drug mentioned in the column in Schedule 4 headed 'Listed Drug'; and

(ii) in the form mentioned in the column in Schedule 4 headed 'Form' for the listed drug mentioned in paragraph (a); and

(iii) with the manner of administration mentioned in the column in Schedule 4 headed 'Manner of administration'; and

(iv) marketed under the brand mentioned in the column in Schedule 4 headed 'Brand' for the listed drug mentioned in subparagraph (i).

46 Patient contributions in relation to approved hospital authorities

(1) This section applies to:

(a) an approved hospital authority for a public hospital that supplies an HSD pharmaceutical benefit to an eligible patient and makes a claim for payment that is not an off-line claim; or

(b) an approved hospital authority for a private hospital that supplies an HSD pharmaceutical benefit to an eligible patient and makes a claim for payment.

(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 subsection 48 (1) if the HSD pharmaceutical benefit is mentioned in paragraph 45 (2) (b).

47 Patient contributions for claims by approved pharmacists

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

(2) The approved pharmacist 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 subsection 48 (1) if the HSD pharmaceutical benefit is mentioned in paragraph 45 (2) (b).

48 Additional patient contributions

(1) For paragraph 45 (2) (b) and subsections 46 (3) and 47 (3), the amount is the amount calculated by subtracting the amount mentioned for the HSD pharmaceutical in the column in Schedule 4 headed 'Approved ex-manufacturer price' from the amount mentioned for the listed drug in the column in Schedule 4 headed 'Claimed ex-manufacturer price'.

(2) However, if the quantity of a listed drug being supplied is for more or less than the quantity mentioned in the column in Schedule 4 headed 'Quantity or Number of Units', the amounts mentioned in the columns in Schedule 4 headed 'Approved ex-manufacturer price' and 'Claimed ex-manufacturer price' must be adjusted proportionally.

Part 7 Miscellaneous

49 Compliance and audit arrangements

(1) If a hospital authority or an approved pharmacist supplies HSD pharmaceutical benefits under this Special Arrangement, the hospital authority or approved pharmacist 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 Medicare Australia CEO on reasonable notice being given to the hospital authority or approved pharmacist.

50 PBS Safety Net

(1) An amount paid by a person because of a charge made by a hospital authority for a public hospital under paragraph 45 (2) (a) for the supply of an HSD pharmaceutical benefit counts towards the person's 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 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

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(b) a reference in the Act or other instrument to a number allotted to an approval under regulation 8A includes a reference to a number allotted to an approval under:

(i) subsection 52 (3) of this Special Arrangement; and

(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 reference in the Act or other instrument to a prescription includes a reference to a medication chart prepared by an eligible medical practitioner at a public hospital in accordance with section 22 of this Special Arrangement; and

(d) a reference in the Act or other instrument to an authority prescription includes a reference to

(i) a prescription under this Special Arrangement for an HSD pharmaceutical benefit that has a CAR drug; and

(ii) a prescription under this Special Arrangement for the supply of an HSD pharmaceutical benefit that has a non-CAR drug to an eligible patient receiving treatment at or from a private hospital; and

(e) a reference in the Act or other instrument to an authority prescription includes a reference to a prescription under this Special Arrangement for an HSD pharmaceutical benefit that has a non-CAR drug above the maximum quantity or maximum number of repeats.

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

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

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 Medicare Australia CEO 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 Medicare Australia CEO may, in writing, approve the hospital authority for this Special Arrangement.

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

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

(a) subsection (3) of this section;

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

(5) The approval may be subject to any conditions the Medicare Australia CEO determines.

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

(7) The Medicare Australia CEO 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 Item codes

(1) In any prescription for an HSD pharmaceutical benefit that has a CAR drug written in accordance with the *Special Arrangements — Highly specialised drugs program for public hospitals (PB 125 of 2009)* before their repeal on 1 July 2010, a reference to the drug's item code is, after the commencement of this Special Arrangement, taken to be a reference to the corresponding item code under this Special Arrangement for the processing of any claim under this Special Arrangement.

(2) This section stops having effect on 1 July 2011.

55 Claims lodged but not determined

(1) A claim that was lodged, but not finally determined, under the old Arrangements is, after the commencement of this Special Arrangement, taken to be a claim made, and may be processed, under this Special Arrangement.

(2) This section stops having effect on 1 July 2011.

(3) In this section:

old Arrangements means:

(a) the *Special Arrangements — Highly specialised drugs program for public hospitals* (PB 125 of 2009) as in force immediately before 1 July 2010; and

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

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

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

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

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Abacavir	Tablet 300 mg (as sulfate)	Oral	Ziagen	VI	EMP	C1820 C1821 C3309 C3310		120	5	D
	Oral solution 20 mg (as sulfate) per mL, 240 mL	Oral	Ziagen	VI	EMP	C1820 C1821 C3309 C3310		8	5	D
Abacavir with Lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	Kivexa	VI	EMP	C1822 C1823 C3311 C3312		60	5	D
Abacavir with Lamivudine and Zidovudine	Tablet containing abacavir 300 mg (as sulfate) with lamivudine 150 mg and zidovudine 300 mg	Oral	Trizivir	VI	EMP	C1822 C1823 C3311 C3312		120	5	D
Abatacept	Powder for I.V. infusion 250 mg	Injection	Orencia	BQ	EMP	C3556 C3557 C3558		See Note 1	See Note 2	D
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Humira	AB	EMP	C3527 C3528 C3529 C3530		See Note 1	See Note 2	PB
	Injection 40 mg in 0.8 mL pre-filled syringe	Injection	Humira	AB	EMP	C3527 C3528 C3529 C3530		See Note 1	See Note 2	C
	Injection 40 mg in 0.8 mL pre-filled pen	Injection	Humira	AB	EMP	C3527 C3528 C3529 C3530		See Note 1	See Note 2	C
Adefovir	Tablet containing adefovir dipivoxil 10 mg	Oral	Hepsera	GI	EMP	C2931 C3313		60	5	D
Ambrisentan	Tablet 5 mg	Oral	Volibris	GK	EMP	C3211 C3212 C3213 C3214 C3215		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Tablet 10 mg	Oral	Volibris	GK	EMP	C3211 C3212 C3213 C3214 C3215		See Note 1	See Note 2	D
Apomorphine	Injection containing apomorphine hydrochloride 20 mg in 2 mL	Injection	Apomine	HH	EMP	C1256 C3314		5	0	D
	Injection containing apomorphine hydrochloride 50 mg in 5 mL	Injection	APO-go	HH	EMP	C1256 C3314		5	0	D
	Solution for subcutaneous infusion containing apomorphine hydrochloride 50 mg in 10 mL pre-filled syringe	Injection	Apomine PFS	HH	EMP	C1256 C3314		5	0	D
Atazanavir	Capsule 100 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C1832 C1833 C3315 C3316		120	5	D
	Capsule 150 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C1832 C1833 C3315 C3316		120	5	D
	Capsule 200 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C1832 C1833 C3315 C3316		120	5	D
	Capsule 300 mg (as sulfate)	Oral	Reyataz	BQ	EMP	C1832 C1833 C3315 C3316		60	5	D
Azithromycin	Tablet 600 mg (as dihydrate)	Oral	Zithromax	PF	EMP	C1299 C3317		16	5	PB
Baclofen	Intrathecal injection 10 mg in 5 mL	Injection	Lioresal Intrathecal	NV	EMP	C1637 C1638 C1639 C1640 C3318 C3319 C3320 C3321		10	0	PB
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Tracleer	AT	EMP	C3013 C3155 C3156 C3157 C3158 C3159 C3160 C3161 C3162		See Note 1	See Note 2	D
	Tablet 125 mg (as monohydrate)	Oral	Tracleer	AT	EMP	C3013 C3155 C3156 C3157 C3158 C3159 C3160 C3161 C3162		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Cidofovir	Solution for I.V. infusion 375 mg (anhydrous) in 5 mL single use vial	Injection	Vistide	GI	EMP	C1610 C3322		4	3	D
Cinacalcet	Tablet 30 mg (as hydrochloride)	Oral	Sensipar	AN	EMP	C2893 C2894 C3323 C3324		56	5	C
	Tablet 60 mg (as hydrochloride)	Oral	Sensipar	AN	EMP	C2893 C2894 C3323 C3324		56	5	C
	Tablet 90 mg (as hydrochloride)	Oral	Sensipar	AN	EMP	C2893 C2894 C3323 C3324		56	5	C
Clarithromycin	Tablet 250 mg	Oral	Klacid	AB	EMP	C1434 C3325		100	2	C
	Tablet 500 mg	Oral	Klacid	AB	EMP	C1434 C3325		100	2	PB
Clozapine	Tablet 25 mg	Oral	Clopine 25	HH	EMP	C1826 C1827 C3326 C3327		100	0	D
			Clozaril 25	NV	EMP	C1826 C1827 C3326 C3327		100	0	
	Tablet 50 mg	Oral	Clopine 50	HH	EMP	C1826 C1827 C3326 C3327		100	0	D
	Tablet 100 mg	Oral	Clopine 100	HH	EMP	C1826 C1827 C3326 C3327		100	0	D
			Clozaril 100	NV	EMP	C1826 C1827 C3326 C3327		100	0	
	Tablet 200 mg	Oral	Clopine 200	HH	EMP	C1826 C1827 C3326 C3327		100	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Oral liquid 50 mg per mL, 100 mL	Oral	Clopine Suspension	HH	EMP	C1826 C1827 C3326 C3327		1	0	D
Cyclosporin	Capsule 10 mg	Oral	Neoral 10	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
	Capsule 25 mg	Oral	Cicloral	SZ	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
			Neoral 25	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	
	Capsule 50 mg	Oral	Cicloral	SZ	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C
			Neoral 50	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	
	Capsule 100 mg	Oral	Cicloral	SZ	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Neoral 100	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		120	5	
	Oral liquid 100 mg per mL, 50 mL	Oral	Neoral	NV	EMP	C1654 C1655 C1656 C1657 C1658 C3328 C3329 C3330 C3331 C3332		4	5	C
	Solution concentrate for I.V. infusion 50 mg in 1 mL	Injection	Sandimmun	NV	EMP	C1504 C3333		10	0	PB
Darbepoetin Alfa	Injection 10 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 20 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 20 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C1957 C3334		8	5	D
	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 40 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 40 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C1957 C3334		8	5	D
	Injection 50 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 60 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 60 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C1957 C3334		8	5	D
	Injection 80 micrograms in 0.4 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 80 micrograms in 0.4 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C1957 C3334		8	5	D
	Injection 100 micrograms in 0.5 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 100 micrograms in 0.5 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C1957 C3334		8	5	D
	Injection 150 micrograms in 0.3 mL pre-filled syringe	Injection	Aranesp	AN	EMP	C1957 C3334		8	5	D
	Injection 150 micrograms in 0.3 mL pre-filled injection pen	Injection	Aranesp SureClick	AN	EMP	C1957 C3334		8	5	D
Darunavir	Tablet 150 mg (as ethanolate)	Oral	Prezista	JC	EMP	C3279 C3335		240	5	D
	Tablet 300 mg (as ethanolate)	Oral	Prezista	JC	EMP	C3279 C3335		240	5	D
Deferasirox	Tablet, dispersible, 125 mg	Oral	Exjade	NV	EMP	C2440 C2441 C3336 C3337		168	5	D
	Tablet, dispersible, 250 mg	Oral	Exjade	NV	EMP	C2440 C2441 C3336 C3337		168	5	D
	Tablet, dispersible, 500 mg	Oral	Exjade	NV	EMP	C2440 C2441 C3336 C3337		168	5	D
Deferiprone	Tablet 500 mg	Oral	Ferriprox	OA	EMP	C1911 C1912 C3338 C3339		600	5	D
	Oral solution 100 mg per mL, 250 mL	Oral	Ferriprox	OA	EMP	C1911 C1912 C3338 C3339		5	5	D
Desferrioxamine	Powder for injection containing desferrioxamine mesylate 500 mg	Injection	Desferal 500 mg	NV	EMP	C1085 C3340		400	5	D
			Hospira Pty Limited	HH	EMP	C1085 C3340		400	5	D
	Powder for injection containing desferrioxamine mesylate 2 g	Injection	Desferal 2 g	NV	EMP	C1085 C3340		60	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Hospira Pty Limited	HH	EMP	C1085 C3340		60	5	D
Didanosine	Capsule 125 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C1820 C1821 C3309 C3310		60	5	D
	Capsule 200 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C1820 C1821 C3309 C3310		60	5	D
	Capsule 250 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C1820 C1821 C3309 C3310		60	5	D
	Capsule 400 mg (containing enteric coated beadlets)	Oral	Videx EC	BQ	EMP	C1820 C1821 C3309 C3310		60	5	D
Dornase Alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation	Pulmozyme	RO	EMP	C1507 C3200 C3201 C3202 C3344 C3345 C3346 C3347		60	5	D
Doxorubicin - Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	SH	EMP	C1828 C1829 C3348 C3349		4	5	C
Efavirenz	Tablet 200 mg	Oral	Stocrin	MK	EMP	C1820 C1821 C3309 C3310		180	5	D
	Tablet 600 mg	Oral	Stocrin	MK	EMP	C1820 C1821 C3309 C3310		60	5	D
	Oral solution 30 mg per mL, 180 mL	Oral	Stocrin	MK	EMP	C1820 C1821 C3309 C3310		7	5	D
Emtricitabine	Capsule 200 mg	Oral	Emtriva	GI	EMP	C1820 C1821 C3309 C3310		60	5	D
Enfuvirtide	Pack containing 60 vials powder for injection 90 mg with 60 vials water for injections 1.1 mL (with syringes and swabs)	Injection	Fuzeon	RO	EMP	C2007 C2008 C3350 C3351		2	5	D
Entecavir	Tablet containing entecavir monohydrate 0.5 mg	Oral	Baraclude	BQ	EMP	C2937 C3352		60	5	D
	Tablet containing entecavir monohydrate 1 mg	Oral	Baraclude	BQ	EMP	C2935 C3353		60	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Epoetin Alfa	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 1000	JC	EMP	C1957 C3334		12	5	D
	Injection 2,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 2000	JC	EMP	C1957 C3334		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Eprex 3000	JC	EMP	C1957 C3334		12	5	D
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Eprex 4000	JC	EMP	C1957 C3334		12	5	D
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 5000	JC	EMP	C1957 C3334		12	5	D
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Eprex 6000	JC	EMP	C1957 C3334		12	5	D
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Eprex 8000	JC	EMP	C1957 C3334		12	5	D
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Eprex 10000	JC	EMP	C1957 C3334		12	5	D
	Injection 20,000 units in 0.5 mL pre-filled syringe	Injection	Eprex 20,000	JC	EMP	C1957 C3334		12	5	D
	Injection 30,000 units in 0.75 mL pre-filled syringe	Injection	Eprex 30,000	JC	EMP	C1957 C3334		12	5	D
	Injection 40,000 units in 1 mL pre-filled syringe	Injection	Eprex 40,000	JC	EMP	C1957 C3334		2	5	D
Epoetin Beta	Injection 2,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D
	Injection 4,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D
	Injection 5,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 6,000 units in 0.3 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D
	Injection 10,000 units in 0.6 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D
	Injection 20,000 units in 0.6 mL pre-filled syringe	Injection	NeoRecormon	RO	EMP	C1957 C3334		12	5	D
Epoetin Lambda	Injection 1,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 2,000 units in 1 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 3,000 units in 0.3 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 4,000 units in 0.4 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 5,000 units in 0.5 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 6,000 units in 0.6 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 8,000 units in 0.8 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
	Injection 10,000 units in 1 mL pre-filled syringe	Injection	Novicrit	NV	EMP	C1957 C3334		12	5	D
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium) with diluent	Injection	Flolan	GK	EMP	C3163 C3164 C3165 C3166 C3167		See Note 1	See Note 2	D
	Powder for I.V. infusion 1.5 mg (as sodium) with diluent	Injection	Flolan	GK	EMP	C3163 C3164 C3165 C3166 C3167		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	WX	EMP	C3531 C3532 C3533		See Note 1	See Note 2	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	WX	EMP	C3534		See Note 1	See Note 2	C
	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	WX	EMP	C3534		See Note 1	See Note 2	C
Etravirine	Tablet 100 mg	Oral	Intelence	JC	EMP	C2956 C3354		240	5	D
Everolimus	Tablet 0.25 mg	Oral	Certican	NV	EMP	C1650 C1651 C3355 C3356		120	5	C
	Tablet 0.5 mg	Oral	Certican	NV	EMP	C1650 C1651 C3355 C3356		120	5	C
	Tablet 0.75 mg	Oral	Certican	NV	EMP	C1650 C1651 C3355 C3356		240	5	C
	Tablet 1 mg	Oral	Certican	NV	EMP	C1650 C1651 C3355 C3356		240	5	C
Filgrastim	Injection 300 micrograms in 1 mL	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377		20	11	D

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

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 480 micrograms in 0.5 mL single use pre-filled syringe	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377		20	11	D
Fosamprenavir	Tablet 700 mg (as calcium)	Oral	Telzir	GK	EMP	C1832 C1833 C3315 C3316		120	5	D
	Oral liquid 50 mg (as calcium) per mL, 225 mL	Oral	Telzir	VI	EMP	C1832 C1833 C3315 C3316		8	5	D
Foscarnet	I.V. infusion containing foscarnet sodium 24 mg per mL, 250 mL	Injection	Foscavir	AP	EMP	C1413 C1610 C3322 C3378		6	1	D
Ganciclovir	Powder for I.V. infusion 500 mg (as sodium)	Injection	Cymevene	RO	EMP	C1612 C1830 C1831 C3379 C3380 C3381		10	1	D
	Intravitreal implant 4.5 mg	Implantation	Vitrasert	BU	EMP	C1612 C3379		1	0	D
Ibandronic acid	Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL	Injection	Bondronat	HH	EMP	C1035 C3343		1	11	PB
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation	Ventavis	SC	EMP	C3168 C3169 C3170 C3171		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Indinavir	Capsule 400 mg (as sulfate)	Oral	Crixivan 400 mg	MK	EMP	C1820 C1821 C3309 C3310		360	5	D
Infliximab	Powder for I.V. infusion 100 mg	Injection	Remicade	SH	EMP	C2996 C2997 C2998 C2999 C3000 C3001 C3002 C3003 C3004 C3005 C3006 C3007 C3008 C3259 C3260 C3261 C3262 C3263 C3264 C3452 C3453 C3454 C3455 C3492 C3493 C3494 C3513 C3514 C3515 C3571 C3572 C3581		See Note 1	See Note 2	D
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C1463 C2939 C3382 C3383		30	5	C
	Injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C1463 C2939 C3382 C3383		30	5	C
	Injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C1463 C2939 C3382 C3383		30	5	C
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C1463 C2939 C3382 C3383		30	5	C
Interferon Alfa-2b	Solution for injection 10,000,000 I.U. in 1 mL single dose vial	Injection	Intron A	SH	EMP	C1009 C1463 C2939 C3382 C3383 C3384		15	5	PB
	Solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	SH	EMP	C1009 C1463 C2939 C3382 C3383 C3384		2	5	C
	Solution for injection 18,000,000 I.U. in 3 mL single dose vial	Injection	Intron A	SH	EMP	C1009 C1463 C2939 C3382 C3383 C3384		15	5	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Solution for injection 25,000,000 I.U. in 2.5 mL single dose vial	Injection	Intron A	SH	EMP	C1009 C1463 C2939 C3382 C3383 C3384		15	5	PB
	Solution for injection 30,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	SH	EMP	C1009 C1463 C2939 C3382 C3383 C3384		2	5	C
	Solution for injection 60,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	SH	EMP	C1009 C1463 C2939 C3382 C3383 C3384		2	5	PB
Interferon Gamma-1b	Injection 2,000,000 I.U. in 0.5 mL	Injection	Imukin	BY	EMP	C1058 C3385		12	11	D
Lamivudine	Tablet 100 mg	Oral	Zeffix	GK	EMP	C2932 C3386		56	5	D
	Tablet 150 mg	Oral	3TC	VI	EMP	C1820 C1821 C3309 C3310		120	5	D
	Tablet 300 mg	Oral	3TC	VI	EMP	C1820 C1821 C3309 C3310		60	5	D
	Oral solution 5 mg per mL, 240 mL	Oral	Zeffix	GK	EMP	C2932 C3386		5	5	D
	Oral solution 10 mg per mL, 240 mL	Oral	3TC	VI	EMP	C1820 C1821 C3309 C3310		8	5	D
Lamivudine with Zidovudine	Tablet 150 mg-300 mg	Oral	Combivir	VI	EMP	C1820 C1821 C3309 C3310		120	5	D
Lanreotide	Powder for suspension for injection 30 mg (as acetate) with diluent	Injection	Somatuline LA	IS	EMP	C2619 C3387		2	11	D
	Injection 60 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	EMP	C2620 C2621 C3388 C3389		2	11	D
	Injection 90 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	EMP	C2620 C2621 C3388 C3389		2	11	D
	Injection 120 mg (as acetate) in single dose pre-filled syringe	Injection	Somatuline Autogel	IS	EMP	C2620 C2621 C3388 C3389		2	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Lanthanum	Tablet, chewable, 500 mg (as carbonate hydrate)	Oral	Fosrenol	ZI	EMP	C3103 C3104 C3390 C3391		180	5	C
	Tablet, chewable, 750 mg (as carbonate hydrate)	Oral	Fosrenol	ZI	EMP	C3103 C3104 C3390 C3391		180	5	C
	Tablet, chewable, 1000 mg (as carbonate hydrate)	Oral	Fosrenol	ZI	EMP	C3103 C3104 C3390 C3391		180	5	C
Lenalidomide	Capsule 5 mg	Oral	Revlimid	CJ	EMP	C3204 C3205		See Note 1	See Note 2	D
	Capsule 10 mg	Oral	Revlimid	CJ	EMP	C3204 C3205		See Note 1	See Note 2	D
	Capsule 15 mg	Oral	Revlimid	CJ	EMP	C3204 C3205		See Note 1	See Note 2	D
	Capsule 25 mg	Oral	Revlimid	CJ	EMP	C3204 C3205		See Note 1	See Note 2	D
Lenograstim	Powder for injection 13,400,000 I.U. (105 micrograms)	Injection	Granocyte 13	HH	EMP	C1005 C1046 C1051 C1097 C1140 C1168 C1228 C1238 C1240 C1249 C1274 C1324 C1333 C1555 C3392 C3393 C3394 C3395 C3396 C3397 C3398 C3399 C3400 C3401 C3402 C3403 C3404 C3405		20	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for injection 33,600,000 I.U. (263 micrograms)	Injection	Granocyte 34	HH	EMP	C1005 C1046 C1051 C1097 C1140 C1168 C1228 C1238 C1240 C1249 C1274 C1324 C1333 C1555 C3392 C3393 C3394 C3395 C3396 C3397 C3398 C3399 C3400 C3401 C3402 C3403 C3404 C3405		20	11	D
Lopinavir with Ritonavir	Tablet 100 mg-25 mg	Oral	Kaletra	AB	EMP	C1832 C1833 C3315 C3316		120	5	D
	Tablet 200 mg-50 mg	Oral	Kaletra	AB	EMP	C1832 C1833 C3315 C3316		240	5	D
	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	Oral	Kaletra	AB	EMP	C1832 C1833 C3315 C3316		10	5	D
Maraviroc	Tablet 150 mg	Oral	Celsentri	PF	EMP	C3286 C3406		120	5	D
	Tablet 300 mg	Oral	Celsentri	PF	EMP	C3286 C3406		120	5	D
Methoxy polyethylene glycol-epoetin beta	Injection 30 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D
	Injection 50 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D
	Injection 75 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D
	Injection 100 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 120 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D
	Injection 200 micrograms in 0.3 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D
	Injection 360 micrograms in 0.6 mL pre-filled syringe	Injection	Mircera	RO	EMP	C1957 C3334		2	5	D
Mycophenolic Acid	Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid	Oral	Myfortic	NV	EMP	C1650 C3355		240	5	C
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid	Oral	Myfortic	NV	EMP	C1650 C3355		240	5	C
	Capsule containing mycophenolate mofetil 250 mg	Oral	CellCept	RO	EMP	C1650 C1651 C3355 C3356		600	5	C
	Tablet containing mycophenolate mofetil 500 mg	Oral	CellCept	RO	EMP	C1650 C1651 C3355 C3356		300	5	C
	Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL	Oral	CellCept	RO	EMP	C1650 C1651 C3355 C3356		2	5	C
Natalizumab	Solution concentrate for I.V. infusion 300 mg in 15 mL	Injection	Tysabri	BD	EMP	C3423 C3424 C3425		1	5	D
Nevirapine	Tablet 200 mg	Oral	Viramune	BY	EMP	C1820 C1821 C3309 C3310		120	5	D
	Oral suspension 50 mg (as hemihydrate) per 5 mL, 240 mL	Oral	Viramune	BY	EMP	C1820 C1821 C3309 C3310		10	5	D
Octreotide	Injection 50 micrograms (as acetate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide MaxRx	XF	EMP	C2622 C2623 C3407 C3408		90	11	D
			Sandostatin 0.05	NV	EMP	C2622 C2623 C3407 C3408		90	11	D
	Injection 100 micrograms (as acetate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C2622 C2623 C3407 C3408		90	11	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Octreotide MaxRx	XF	EMP	C2622 C2623 C3407 C3408		90	11	D
			Sandostatin 0.1	NV	EMP	C2622 C2623 C3407 C3408		90	11	D
	Injection 500 micrograms (as acetate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C2622 C2623 C3407 C3408		90	11	D
			Octreotide MaxRx	XF	EMP	C2622 C2623 C3407 C3408		90	11	D
			Sandostatin 0.5	NV	EMP	C2622 C2623 C3407 C3408		90	11	D
	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	EMP	C2624 C2625 C3409 C3410		1	11	D
	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	EMP	C2624 C2625 C3409 C3410		1	11	D
	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	Injection	Sandostatin LAR	NV	EMP	C2624 C2625 C3409 C3410		1	11	D
Pamidronic Acid	Concentrated injection containing disodium pamidronate 15 mg in 5 mL	Injection	Pamisol	HH	EMP	C1500 C3341		4	2	C
	Injection set containing 4 vials powder for I.V. infusion containing disodium pamidronate 15 mg and 4 ampoules solvent 5 mL	Injection	Aredia 15 mg	NV	EMP	C1500 C3341		1	2	C
	Concentrated injection containing disodium pamidronate 30 mg in 10 mL	Injection	Pamisol	HH	EMP	C1500 C3341		2	2	C
	Injection set containing 2 vials powder for I.V. infusion containing disodium pamidronate 30 mg and 2 ampoules solvent 10 mL	Injection	Aredia 30 mg	NV	EMP	C1500 C3341		1	2	C
	Concentrated injection containing disodium pamidronate 60 mg in 10 mL	Injection	Pamisol	HH	EMP	C1500 C3341		1	2	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Concentrated injection containing disodium pamidronate 90 mg in 10 mL	Injection	Pamisol	HH	EMP	C1035 C1233 C1500 C3341 C3342 C3343		1	11	C
	Injection set containing 1 vial powder for I.V. infusion containing disodium pamidronate 90 mg and 1 ampoule solvent 10 mL	Injection	Aredia 90 mg	NV	EMP	C1035 C1233 C1500 C3341 C3342 C3343		1	11	C
Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe	Injection	Neulasta	AN	EMP	C2912 C2917 C2918 C2919 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3362 C3363 C3364 C3365 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377		1	11	D
Peginterferon Alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	EMP	C2334 C2940 C3411 C3412		8	5	D
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe	Injection	Pegasys	RO	EMP	C2334 C2940 C3411 C3412		8	5	D
Peginterferon Alfa-2b	Powder for injection 50 micrograms with diluent in single use injection pen	Injection	PEG-Intron Redipen	SH	EMP	C2334 C3412		8	5	D
	Powder for injection 80 micrograms with diluent in single use injection pen	Injection	PEG-Intron Redipen	SH	EMP	C2334 C3412		8	5	D
	Powder for injection 100 micrograms with diluent in single use injection pen	Injection	PEG-Intron Redipen	SH	EMP	C2334 C3412		8	5	D
	Powder for injection 120 micrograms with diluent in single use injection pen	Injection	PEG-Intron Redipen	SH	EMP	C2334 C3412		8	5	D
	Powder for injection 150 micrograms with diluent in single use injection pen	Injection	PEG-Intron Redipen	SH	EMP	C2334 C3412		8	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Raltegravir	Tablet 400 mg (as potassium)	Oral	Isentress	MK	EMP	C3505 C3506 C3507 C3508		120	5	D
Ribavirin and Peginterferon Alfa-2a	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 135 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 112 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 140 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 168 tablets ribavirin 200 mg and 4 pre-filled syringes peginterferon alfa-2a injection 180 micrograms	Injection/oral	Pegasys RBV	RO	EMP	C3053 C3055 C3413 C3414		2	5	D
Ribavirin and Peginterferon Alfa-2b	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 50 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 80 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 112 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 100 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 120 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 84 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 140 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 168 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
	Pack containing 196 capsules ribavirin 200 mg and 4 single use injection pens containing peginterferon alfa-2b powder for injection 150 micrograms with diluent	Injection/oral	Pegatron	SH	EMP	C3053 C3055 C3413 C3414		2	5	D
Rifabutin	Capsule 150 mg	Oral	Mycobutin	PF	EMP	C1299 C1435 C3317 C3415		120	5	D
Ritonavir	Tablet 100 mg	Oral	Norvir	AB	EMP	C1820 C1821 C3309 C3310		720	5	D
	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	Oral	Norvir	AB	EMP	C1820 C1821 C3309 C3310		10	5	D
Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	RO	EMP	C3573 C3574 C3582		See Note 1	See Note 2	C
Saquinavir	Tablet 500 mg (as mesylate)	Oral	Invirase	RO	EMP	C1820 C1821 C3309 C3310		240	5	D
Sevelamer	Tablet containing sevelamer hydrochloride 800 mg	Oral	Renagel	GZ	EMP	C3103 C3104 C3390 C3391		360	5	C
Sildenafil	Tablet 20 mg (as citrate)	Oral	Revatio	PF	EMP	C3172 C3173 C3174 C3175		See Note 1	See Note 2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Sirolimus	Tablet 1 mg	Oral	Rapamune	WX	EMP	C1650 C3355		200	5	C
	Tablet 2 mg	Oral	Rapamune	WX	EMP	C1650 C3355		200	5	C
	Oral solution 1 mg per mL, 60 mL	Oral	Rapamune	WX	EMP	C1650 C3355		2	5	C
Sitaxentan	Tablet containing sitaxentan sodium 100 mg	Oral	Thelin	PF	EMP	C3176 C3177 C3178 C3179		See Note 1	See Note 2	D
Stavudine	Capsule 20 mg	Oral	Zerit	BQ	EMP	C1820 C1821 C3309 C3310		120	5	D
	Capsule 30 mg	Oral	Zerit	BQ	EMP	C1820 C1821 C3309 C3310		120	5	D
	Capsule 40 mg	Oral	Zerit	BQ	EMP	C1820 C1821 C3309 C3310		120	5	D
	Powder for oral solution 1 mg per mL, 200 mL	Oral	Zerit	BQ	EMP	C1820 C1821 C3309 C3310		24	5	D
Tacrolimus	Capsule 500 micrograms	Oral	Prograf	JC	EMP	C1654 C3328		200	5	C
			Tacrolimus Sandoz	SZ	EMP	C1654 C3328		200	5	C
	Capsule 1 mg	Oral	Prograf	JC	EMP	C1654 C3328		200	5	C
			Tacrolimus Sandoz	SZ	EMP	C1654 C3328		200	5	C
	Capsule 5 mg	Oral	Prograf	JC	EMP	C1654 C3328		100	5	C
			Tacrolimus Sandoz	SZ	EMP	C1654 C3328		100	5	C
	Capsule 0.5 mg (once daily prolonged release)	Oral	Prograf XL	JC	EMP	C1654 C3328		60	5	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Capsule 1 mg (once daily prolonged release)	Oral	Prograf XL	JC	EMP	C1654 C3328		120	5	C
	Capsule 5 mg (once daily prolonged release)	Oral	Prograf XL	JC	EMP	C1654 C3328		60	5	C
Telbivudine	Tablet 600 mg	Oral	Sebivo	NV	EMP	C3052 C3416		56	5	D
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg	Oral	Viread	GI	EMP	C1820 C1821 C2931 C3203 C3309 C3310 C3313 C3417		60	5	D
Tenofovir with Emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	Truvada	GI	EMP	C1820 C1821 C3309 C3310		60	5	D
Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg	Oral	Atripla	GI	EMP	C1820 C1821 C3309 C3310		60	5	D
Thalidomide	Capsule 50 mg	Oral	Thalomid	CJ	EMP	C1233 C3342		112	0	D
	Capsule 100 mg	Oral	Thalomid	CJ	EMP	C1233 C3342		56	0	D
Tipranavir	Capsule 250 mg	Oral	Aptivus	BY	EMP	C2700 C3418		240	5	D
	Oral liquid 100 mg per mL, 95 mL	Oral	Aptivus	BY	EMP	C3500 C3501		7	5	D
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Actemra	RO	EMP	C3480 C3559 C3560 C3561		See Note 1	See Note 2	D
	Concentrate for injection 200 mg in 10 mL	Injection	Actemra	RO	EMP	C3480 C3559 C3560 C3561		See Note 1	See Note 2	D
	Concentrate for injection 400 mg in 20 mL	Injection	Actemra	RO	EMP	C3480 C3559 C3560 C3561		See Note 2	See Note 2	D
Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valtrex	GK	EMP	C1494 C3419		500	2	C

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Valganciclovir	Tablet 450 mg (as hydrochloride)	Oral	Valcyte	RO	EMP	C1620 C1964 C3420 C3421		120	5	D
	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	Oral	Valcyte	RO	EMP	C1620 C1964 C3420 C3421		11	5	D
Zidovudine	Capsule 100 mg	Oral	Retrovir	GK	EMP	C1820 C1821 C3309 C3310		400	5	D
	Capsule 250 mg	Oral	Retrovir	GK	EMP	C1820 C1821 C3309 C3310		240	5	D
	Syrup 10 mg per mL, 200 mL	Oral	Retrovir	GK	EMP	C1820 C1821 C3309 C3310		15	5	D
Zoledronic Acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	Injection	Zometa	NV	EMP	C1035 C1233 C1500 C1797 C3341 C3342 C3343 C3422		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

(section 7)

Code	Responsible Person	Australian Business Number
AB	Abbott Australasia Pty Ltd	95 000 180 389
AN	Amgen Australia Pty Limited	31 051 057 428
AP	AstraZeneca Pty Ltd	54 009 682 311
AT	Actelion Pharmaceuticals Australia Pty Ltd	32 097 278 512
BD	Biogen Idec Australia Pty Ltd	30 095 760 115
BQ	Bristol-Myers Squibb Australia Pty Ltd	33 004 333 322
BU	Bausch & Lomb (Australia) Pty Ltd	34 000 650 251
BY	Boehringer Ingelheim Pty Ltd	52 000 452 308
CJ	Celgene Pty Limited	42 118 998 771
GI	Gilead Sciences Pty Limited	71 072 611 708
GK	GlaxoSmithKline Australia Pty Ltd	47 100 162 481
GZ	Genzyme Australasia Pty Ltd	24 083 420 526
HH	Hospira Pty Limited	13 107 058 328
IS	Ipsen Pty Ltd	47 095 036 909
JC	Janssen-Cilag Pty Ltd	47 000 129 975
MK	Merck Sharp & Dohme (Australia) Pty Ltd	14 000 173 508
NV	Novartis Pharmaceuticals Australia Pty Limited	18 004 244 160
OA	Orphan Australia Pty Ltd	11 067 189 342
PF	Pfizer Australia Pty Ltd	50 008 422 348
PF	ViiV Healthcare Pty Ltd	46 138 687 448
RO	Roche Products Pty Ltd	70 000 132 865
SC	Bayer Australia Ltd	22 000 138 714
SH	Schering-Plough Pty Limited	57 000 235 245
SZ	Sandoz Pty Ltd	60 075 449 553
VI	ViiV Healthcare Pty Ltd	46 138 687 448
WX	Wyeth Australia Pty Limited	16 000 296 211
XF	Max Pharma Pty Ltd	93 121 857 878
ZI	Shire Australia Pty Limited	29 128 941 819

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	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Abacavir with Lamivudine	C1822		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1823		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures

	C3311		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3311
	C3312		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3312
Abacavir with Lamivudine and Zidovudine	C1822		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1823		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3311		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3311
	C3312		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients over 12 years of age, weighing 40 kg or more, with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3312
Abatacept	C3556		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 1 (new patient or patient recommencing after a break of more than 12 months) Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have severe active rheumatoid arthritis; and (b) have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 12 months; and	Compliance with modified Authority Required procedures

			(c) have failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include: (i) 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: — hydroxychloroquine at a dose of at least 200 mg daily; or — leflunomide at a dose of at least 10 mg daily; or — sulfasalazine at a dose of at least 2 g daily; or (ii) if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose — at least 3 months continuous treatment with each of at least 2 of the following DMARDs: — hydroxychloroquine at a dose of at least 200 mg daily; and/or — leflunomide at a dose of at least 10 mg daily; and/or — sulfasalazine at a dose of at least 2 g daily; or (iii) 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 — at least 3 months continuous treatment with each of at least 2 DMARDs, one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: — azathioprine at a dose of at least 1 mg/kg per day; and/or — cyclosporin at a dose of at least 2 mg/kg/day; and/or — sodium aurothiomalate at a dose of 50 mg weekly; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, infliximab, golimumab, rituximab or tocilizumab; and where the following conditions apply: if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the authority application includes details of the contraindication or intolerance to methotrexate, and documents the maximum tolerated dose of methotrexate, if applicable; the authority application includes 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, the authority application provides details of the contraindication or intolerance and dose for each DMARD; failure to achieve an adequate response to the DMARD treatment specified above is demonstrated by the following: (a) 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 (b) either: (i) a total active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is 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 are determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy, and all measures are 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 authority application states the reason this criterion cannot be satisfied;	

			the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgement; a patient is eligible for treatment if they have not failed previous PBS-subsidised treatment with abatacept for rheumatoid arthritis, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; a course of initial treatment is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	
	C3557		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 2 (change or recommencement after a break of less than 12 months) Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have a documented history of severe active rheumatoid arthritis; and (b) have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition within the previous 12 months and are eligible to receive further bDMARD therapy; and (c) have not failed previous PBS-subsidised treatment with abatacept for this condition; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: patients are eligible to receive further bDMARD therapy for rheumatoid arthritis provided they have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; patients who demonstrate a response to a course of PBS-subsidised treatment with rituximab and who wish to transfer to treatment with abatacept are not eligible to commence treatment with abatacept until they have completed a period free from PBS-subsidised bDMARD treatment of at least 22 weeks duration, immediately following the second rituximab infusion; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with abatacept and wishes to recommence therapy with this drug, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised abatacept treatment; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised abatacept treatment is a 16-week initial treatment course, is made following a minimum of 12 weeks of therapy; a course of initial treatment is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	Compliance with modified Authority Required procedures
	C3558		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — continuing treatment Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with abatacept; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment was with abatacept; and	Compliance with modified Authority Required procedures

			where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: an adequate response to treatment is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and 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 an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with abatacept; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of abatacept therapy is a 16-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
Adalimumab	C3527		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — initial treatment 1 (new patient or patient recommencing after a break of more than 12 months) Initial treatment commencing a treatment cycle, by a paediatric rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years: (a) who has severe active juvenile idiopathic arthritis; and (b) whose parent or authorised guardian has signed a patient acknowledgement; and (c) who has not received PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 12 months; and (d) who has demonstrated either: (i) severe intolerance of, or toxicity due to, methotrexate; or (ii) failure to achieve an adequate response to 1 or more of the following treatment regimens: — 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 — 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 where bDMARD means adalimumab or etanercept; and	Compliance with modified Authority Required procedures

			where the following conditions apply: severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs 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 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 Therapeutic Goods Administration-approved Product Information, the authority application provides details of the contraindication; if intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, the authority application provides details of this toxicity; failure to achieve an adequate response is indicated by the following criteria and must be demonstrated in all patients at the time of the authority 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 active if swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as active if there is 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 is performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form and an acknowledgement signed by a parent or authorised guardian; a patient whose previous treatment cycle was ceased due to their failure to respond to bDMARD treatment 3 times (twice with one agent and once with the other) is eligible to commence a new treatment cycle with an initial course of adalimumab provided a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under the new treatment cycle; a course of initial treatment commencing a treatment cycle is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	
	C3528		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — initial treatment 2 (change or recommencement after a break of less than 12 months) Initial PBS-subsidised treatment, or recommencement of treatment, with adalimumab within an ongoing treatment cycle, by a paediatric rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who: (a) has a documented history of severe active juvenile idiopathic arthritis; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with adalimumab in this treatment cycle and wishes to recommence	Compliance with Written or Telephone Authority Required procedures

			therapy with this drug, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised adalimumab treatment is a 16 week initial treatment course, is made following a minimum of 12 weeks of therapy; a patient who has failed to respond to treatment with adalimumab and etanercept 3 times (twice with one agent and once with the other) is not eligible to receive further PBS-subsidised therapy in this treatment cycle; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	
	C3529		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — initial treatment 3 Commencement of a treatment cycle with an initial PBS-subsidised course of adalimumab for continuing treatment, by a paediatric rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who: (a) has a documented history of severe active juvenile idiopathic arthritis; and (b) was receiving treatment with adalimumab prior to 1 March 2010; and (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab; and (d) is receiving treatment with adalimumab at the time of application; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form and an acknowledgement signed by a parent or authorised guardian; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; a patient is eligible for PBS-subsidised treatment under the above criteria once only	Compliance with modified Authority Required procedures
	C3530		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — continuing treatment Continuing PBS-subsidised treatment with adalimumab within an ongoing treatment cycle, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient: (a) who has a documented history of severe active juvenile idiopathic arthritis; and (b) who has demonstrated an adequate response to treatment with adalimumab; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle was with adalimumab; and where bDMARD means adalimumab or etanercept; and where the following conditions apply: an adequate response to treatment is defined as: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder, cervical spine and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint	Compliance with modified Authority Required procedures

			destruction or bony overgrowth); the same joints assessed to establish baseline joint count at the commencement of an initial course of treatment are assessed to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with adalimumab; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of adalimumab therapy is a 16 week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a patient who has failed to respond to bDMARD treatment 3 times (twice with one agent and once with the other) is not eligible to receive further PBS-subsidised therapy in this treatment cycle; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
Adefovir	C2931		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) 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 (b) 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; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures
	C3313		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) 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 (b) 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; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3313

Ambrisentan			**Definitions** For the purpose of PBS-subsidised supply of ambrisentan for C3211, C3212, C3213, C3214 and C3215: ***"PAH agent"*** means ambrisentan, bosentan, epoprostenol, iloprost, sildenafil or sitaxentan ***"Primary pulmonary hypertension and pulmonary arterial hypertension secondary to connective tissue disease"*** means: (i) pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or (iii) where right heart catheterisation cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function ***"Response to ambrisentan or prior vasodilator treatment"*** means: (i) for adult patients with 2 or more baseline tests – as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (ii) for adult patients with an RHC composite assessment alone at baseline – as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iii) for adult patients with an ECHO composite assessment alone at baseline – as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iv) for patients aged less than 18 years – as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital	
	C3211		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 1 (new patients) Initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; and where the patient has failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds:	Compliance with modified Authority Required procedures

			(i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) details of prior vasodilator treatment, including the dose and duration of treatment; and (4) where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information, details on the nature of the adverse event or contraindication; and (5) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3212		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 2 (new patients) Initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; or (c) WHO Functional Class IV primary pulmonary hypertension; or (d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite	Compliance with modified Authority Required procedures

			assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3213		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (previous treatment not PBS-subsidised) Initial PBS-subsidised treatment with ambrisentan of patients who were receiving treatment with ambrisentan prior to 1 December 2009 and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension; or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; or (c) WHO Functional Class IV primary pulmonary hypertension; or (d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; and where the following conditions apply: the authority application is made in writing and includes: (1) for patients who have received less than 6 months of ambrisentan treatment at the time of application — a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT) at the time treatment with ambrisentan was commenced, or, where results from all 3 of the tests are not available or it was not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or	Compliance with modified Authority Required procedures

			(v) ECHO composite assessment alone; and (2) the date of commencement of ambrisentan treatment; and (3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (4) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; for patients who have received less than 6 months of non-PBS-subsidised ambrisentan treatment at the time of application — the maximum duration of treatment which will be authorised under this criterion is sufficient to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy; if the duration of treatment authorised for the written application under this criterion is less than that to which the patient is entitled, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete the maximum allowable duration of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3214		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for all patients) Initial treatment with ambrisentan of patients: (a) who have primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with ambrisentan; or (b) who have primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures

	C3215		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment (all patients) Continuing PBS-subsidised treatment with ambrisentan of patients who have received approval for initial PBS-subsidised treatment with ambrisentan and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of ambrisentan treatment; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that the test results included in the application are from the same tests as were conducted at baseline, except for patients who were able to undergo all 3 tests at baseline and whose subsequent ECHO composite assessment and 6MWT results demonstrate disease stability or improvement, in which case RHC composite assessment can be omitted: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) ECHO composite assessment plus 6MWT; or (iv) RHC composite assessment alone; or (v) ECHO composite assessment alone; and (2) where the same test or tests conducted at baseline cannot be performed on clinical grounds for assessment of response, a patient specific reason why the test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures
Apomorphine	C1256		Where the patient is receiving treatment at/from a private hospital Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy	Compliance with Written or Telephone Authority Required procedures
	C3314		Where the patient is receiving treatment at/from a public hospital Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3314

Atazanavir	C1832		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1833		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3315		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3315
	C3316		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3316
Azithromycin	C1299		Where the patient is receiving treatment at/from a private hospital Prophylaxis against *Mycobacterium avium* complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C3317		Where the patient is receiving treatment at/from a public hospital Prophylaxis against *Mycobacterium avium* complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3317
Baclofen	C1637		Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin	Compliance with Written or Telephone Authority Required procedures
	C1638		Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis	Compliance with Written or Telephone Authority Required procedures
	C1639		Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury	Compliance with Written or Telephone Authority Required procedures

	C1640		Where the patient is receiving treatment at/from a private hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease	Compliance with Written or Telephone Authority Required procedures
	C3318		Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3318
	C3319		Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3319
	C3320		Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3320
	C3321		Where the patient is receiving treatment at/from a public hospital Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3321
Bosentan			**Definitions** For the purpose of PBS-subsidised supply of bosentan for C3013, C3155, C3156, C3157, C3158, C3159, C3160, C3161 and C3162: ***"PAH agent"*** means ambrisentan, bosentan, epoprostenol, iloprost, sildenafil or sitaxentan ***"Primary pulmonary hypertension, pulmonary arterial hypertension secondary to scleroderma and pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology)"*** means: (i) pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less	

			than 18 mmHg; or (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or (iii) where right heart catheterisation cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function ***"Response to bosentan or prior vasodilator treatment"*** means: (i) for adult patients with 2 or more baseline tests – as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (ii) for adult patients with an RHC composite assessment alone at baseline – as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iii) for adult patients with an ECHO composite assessment alone at baseline – as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iv) for patients aged less than 18 years – as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital	
	C3013		Where the patient is receiving treatment at/from a private or public hospital Cessation of treatment (all patients) Final PBS-subsidised supply to allow for gradual cessation of treatment for patients with World Health Organisation (WHO) Functional Class III or IV primary pulmonary hypertension, or WHO Functional Class III or IV pulmonary arterial hypertension secondary to scleroderma, or WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who have not responded to bosentan monohydrate therapy; and where the following conditions apply: the authority application may be submitted by telephone; the supply authorised under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient to allow gradual dose reduction over a period of 1 month	Compliance with modified Authority Required procedures
	C3155		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 1 (new adult patient) Initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; and where the patient has failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; and	Compliance with modified Authority Required procedures

			where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) details of prior vasodilator treatment, including the dose and duration of treatment; and (4) where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information, details on the nature of the adverse event or contraindication; and (5) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3156		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 2 (new adult patient) Initial PBS-subsidised treatment with bosentan monohydrate of adult patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to scleroderma and a mean right atrial pressure	Compliance with modified Authority Required procedures

			greater than 8 mmHg, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; or (c) WHO Functional Class IV primary pulmonary hypertension; or (d) WHO Functional Class IV pulmonary arterial hypertension secondary to scleroderma; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3157		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 1 (new patient under 18 years of age) Initial PBS-subsidised treatment with bosentan monohydrate of patients aged less than 18 years who have not received prior PBS-subsidised treatment with a PAH agent, who have been assessed by a physician from a designated hospital to have World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and either a mean right atrial pressure of 8 mmHg or less, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO), and who have failed to respond to 6 or more weeks of appropriate prior vasodilator treatment unless intolerance or a contraindication to such treatment exists;	Compliance with modified Authority Required procedures

			and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a patient and prescriber acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) details of prior vasodilator treatment, including the dose and duration of treatment; and (4) where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information, details on the nature of the adverse event or contraindication; and (5) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3158		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 2 (new patient under 18 years of age) Initial PBS-subsidised treatment with bosentan monohydrate of patients aged less than 18 years who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and either a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on	Compliance with modified Authority Required procedures

			clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class IV primary pulmonary hypertension; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a patient and prescriber acknowledgment, signed by the parent or authorised guardian, indicating that they understand and acknowledge that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3159		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (new patient) Initial PBS-subsidised treatment with bosentan monohydrate of a patient who has been assessed by a physician from a designated hospital to have World Health Organisation (WHO) Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology); and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO)	Compliance with modified Authority Required procedures

			composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment (and signed by the parent or authorised guardian for patients under 18 years of age) indicating that the patient understands and acknowledges that PBS-subsidised treatment with bosentan monohydrate will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3160		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for adult patients) Initial treatment with bosentan monohydrate of adult patients: (a) who have primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; or (b) who have primary pulmonary hypertension or pulmonary arterial hypertension secondary to scleroderma and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than bosentan monohydrate; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and	Compliance with modified Authority Required procedures

			(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3161		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for patients under 18 years of age) Initial treatment with bosentan monohydrate of patients aged less than 18 years: (a) who have primary pulmonary hypertension, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), who wish to re-commence PBS-subsidised bosentan monohydrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with bosentan monohydrate; or (b) who have primary pulmonary hypertension and whose most recent course of PBS-subsidised treatment was with a PAH agent other than bosentan monohydrate; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; the first supply authorised for the written application under this criterion is limited to the provision of a quantity of the 62.5 mg strength tablet sufficient for 1 month of treatment; the second supply authorised for the written application under this criterion provides for up to a maximum of 5 months of treatment with the 62.5 mg or the 125 mg strength tablet; if less than 5 months of treatment is authorised for the second supply under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 5 months of treatment may be submitted by	Compliance with modified Authority Required procedures

			telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3162		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment (all patients) Continuing PBS-subsidised treatment with bosentan monohydrate of patients who have received approval for initial PBS-subsidised treatment with bosentan monohydrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of bosentan monohydrate treatment; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that the test results included in the application are from the same tests as were conducted at baseline, except for patients who were able to undergo all 3 tests at baseline and whose subsequent ECHO composite assessment and 6MWT results demonstrate disease stability or improvement, in which case RHC composite assessment can be omitted: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) ECHO composite assessment plus 6MWT; or (iv) RHC composite assessment alone; or (v) ECHO composite assessment alone; and (2) where the same test or tests conducted at baseline cannot be performed on clinical grounds for assessment of response, a patient specific reason why the test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the 62.5 mg or the 125 mg strength tablet sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures
Cidofovir	C1610		Where the patient is receiving treatment at/from a private hospital Treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome	Compliance with Written or Telephone Authority Required procedures

	C3322		Where the patient is receiving treatment at/from a public hospital Treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3322
Cinacalcet	C2893		Where the patient is receiving treatment at/from a private hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (iPTH) of at least 50 pmol per L, not responding to conventional therapy	Compliance with Written or Telephone Authority Required procedures
	C2894		Where the patient is receiving treatment at/from a private hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (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, not responding to conventional treatment	Compliance with Written or Telephone Authority Required procedures
	C3323		Where the patient is receiving treatment at/from a public hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (iPTH) of at least 50 pmol per L, not responding to conventional therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3323
	C3324		Where the patient is receiving treatment at/from a public hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (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, not responding to conventional treatment	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3324
Clarithromycin	C1434		Where the patient is receiving treatment at/from a private hospital Treatment of *Mycobacterium avium* complex infections	Compliance with Written or Telephone Authority Required procedures
	C3325		Where the patient is receiving treatment at/from a public hospital Treatment of *Mycobacterium avium* complex infections	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3325

Clozapine	C1826		Where the patient is receiving treatment at/from a private hospital Schizophrenia in patients who are non-responsive to other neuroleptic agents	Compliance with Written or Telephone Authority Required procedures
	C1827		Where the patient is receiving treatment at/from a private hospital Schizophrenia in patients who are intolerant of other neuroleptic agents	Compliance with Written or Telephone Authority Required procedures
	C3326		Where the patient is receiving treatment at/from a public hospital Schizophrenia in patients who are non-responsive to other neuroleptic agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3326
	C3327		Where the patient is receiving treatment at/from a public hospital Schizophrenia in patients who are intolerant of other neuroleptic agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3327
Cyclosporin	C1504		Where the patient is receiving treatment at/from a private hospital For use by organ or tissue transplant recipients	Compliance with Written or Telephone Authority Required procedures
	C1654		Where the patient is receiving treatment at/from a private hospital Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C1655		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures
	C1656		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life	Compliance with Written or Telephone Authority Required procedures
	C1657		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired	Compliance with Written or Telephone Authority Required procedures

	C1658		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures
	C3328		Where the patient is receiving treatment at/from a public hospital Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3328
	C3329		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3329
	C3330		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3330
	C3331		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3331
	C3332		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3332

	C3333		Where the patient is receiving treatment at/from a public hospital For use by organ or tissue transplant recipients	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3333
Darbepoetin Alfa	C1957		Where the patient is receiving treatment at/from a private hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.	Compliance with Written or Telephone Authority Required procedures
	C3334		Where the patient is receiving treatment at/from a public hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3334
Darunavir	C3279		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of human immunodeficiency virus (HIV) infection in an antiretroviral experienced patient with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre; a patient must have failed previous treatment with, or have resistance to, 1 antiretroviral regimen	Compliance with Written or Telephone Authority Required procedures
	C3335		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily, of human immunodeficiency virus (HIV) infection in an antiretroviral experienced patient with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. A patient must have failed previous treatment with, or have resistance to, 1 antiretroviral regimen	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3335
Deferasirox	C2440		Where the patient is receiving treatment at/from a private hospital Chronic iron overload in adults, adolescents and children 6 years and older associated with disorders of erythropoiesis;	Compliance with Written or Telephone Authority Required procedures
	C2441		Where the patient is receiving treatment at/from a private hospital Chronic iron overload in paediatric patients aged 2 to 5 years, associated with disorders of erythropoiesis, who are intolerant to desferrioxamine or in whom desferrioxamine has proven ineffective.	Compliance with Written or Telephone Authority Required procedures
	C3336		Where the patient is receiving treatment at/from a public hospital Chronic iron overload in adults, adolescents and children 6 years and older associated with disorders of erythropoiesis	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3336

	C3337		Where the patient is receiving treatment at/from a public hospital Chronic iron overload in paediatric patients aged 2 to 5 years, associated with disorders of erythropoiesis, who are intolerant to desferrioxamine or in whom desferrioxamine has proven ineffective	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3337
Deferiprone	C1911		Where the patient is receiving treatment at/from a private hospital Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy;	Compliance with Written or Telephone Authority Required procedures
	C1912		Where the patient is receiving treatment at/from a private hospital Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective.	Compliance with Written or Telephone Authority Required procedures
	C3338		Where the patient is receiving treatment at/from a public hospital Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3338
	C3339		Where the patient is receiving treatment at/from a public hospital Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3339
Desferrioxamine	C1085		Where the patient is receiving treatment at/from a private hospital Disorders of erythropoiesis associated with treatment-related chronic iron overload.	Compliance with Written or Telephone Authority Required procedures
	C3340		Where the patient is receiving treatment at/from a public hospital Disorders of erythropoiesis associated with treatment-related chronic iron overload	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3340
Didanosine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures

	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Dornase Alfa	C1507		Where the patient is receiving treatment at/from a private hospital Patient 5 years of age or older Use by cystic fibrosis patients who satisfy all of the following criteria: (1) are 5 years of age or older; (2) have a FVC greater than 40% predicted for age, gender and height; (3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease); (4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial. In order for patients to be eligible for participation in the highly specialised drugs (HSD) program, the following conditions must be met: (1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit; (2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation; (3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease; (4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily; (5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily; (6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial;	Compliance with Written or Telephone Authority Required procedures

			(7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals; (8) Other aspects of treatment, such as physiotherapy, must be continued; (9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)	
	C3200		Where the patient is receiving treatment at/from a private hospital Patient less than 5 years of age Treatment of cystic fibrosis in a patient less than 5 years of age who has: (1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or (2) Significant bronchiectasis on chest high resolution computed tomography scan; or (3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or (4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. In order for the patient to be eligible for participation in the highly specialised drugs (HSD) program, the following conditions must be met: (1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit; (2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly	Compliance with Written or Telephone Authority Required procedures
	C3201		Where the patient is receiving treatment at/from a private hospital Patient 5 years of age or older (commenced treatment at age of less than 5 years) Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5 years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use	Compliance with Written or Telephone Authority Required procedures
	C3202		Where the patient is receiving treatment at/from a private hospital Patient less than 5 years of age (treatment initiated prior to 1 November 2009) Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is	Compliance with Written or Telephone Authority Required procedures

			continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use	
	C3344		Where the patient is receiving treatment at/from a public hospital Patient 5 years of age or older Use by cystic fibrosis patients who satisfy all of the following criteria: (1) are 5 years of age or older; (2) have a FVC greater than 40% predicted for age, gender and height; (3) have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease); (4) are participating in a 4 week trial as detailed below or have achieved a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) after a 4 week trial. In order for patients to be eligible for participation in the highly specialised drugs (HSD) program, the following conditions must be met: (1) Patients must be assessed at cystic fibrosis clinics/centres which are under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such units is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit; (2) The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at established lung function testing laboratories, unless this is not possible because of geographical isolation; (3) Prior to dornase alfa therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease; (4) Initial therapy is limited to 4 weeks' treatment with dornase alfa at a dose of 2.5 mg daily; (5) At or towards the end of the initial 4 weeks' trial, patients must be reassessed and a further FEV1 measurement be undertaken (single test under conditions as above). Patients who achieve a 10% or greater improvement in FEV1 (compared to baseline established prior to dornase alfa treatment) are eligible for continued subsidy under the HSD program at a dose of 2.5 mg daily; (6) Patients who fail to meet a 10% or greater improvement in FEV1 after the initial 4 weeks' treatment at a dose of 2.5 mg daily, may have 1 further trial in the next 12 months but not before 3 months after the initial trial; (7) Following an initial 6 months' therapy, a global assessment must be undertaken involving the patient, the patient's family (in the case of paediatric patients) and the treating physician(s) to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. (Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.) Further reassessments are to be undertaken at six-monthly intervals; (8) Other aspects of treatment, such as physiotherapy, must be continued; (9) Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy (i.e. satisfied the criteria for the 4 week trial and achieved a 10% or greater improvement in FEV1) then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3344

	C3345		Where the patient is receiving treatment at/from a public hospital Patient less than 5 years of age Treatment of cystic fibrosis in a patient less than 5 years of age who has: (1) A severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring frequent hospital admissions more frequently than 3 times per year; or (2) Significant bronchiectasis on chest high resolution computed tomography scan; or (3) Severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or (4) Severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy. In order for the patient to be eligible for participation in the highly specialised drugs (HSD) program, the following conditions must be met: (1) The patient must be assessed at a cystic fibrosis clinic/centre which is under the supervision of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis, and the prescribing of dornase alfa under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by specialist physician or paediatrician in consultation with such a unit; (2) Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. Further reassessments are to be undertaken and documented yearly	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3345
	C3346		Where the patient is receiving treatment at/from a public hospital Patient 5 years of age or older (commenced treatment at age of less than 5 years) Continuation of treatment of cystic fibrosis in a patient 5 years of age or older, who initiated treatment with dornase alfa at an age of less than 5 years and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3346
	C3347		Where the patient is receiving treatment at/from a public hospital Patient less than 5 years of age (treatment initiated prior to 1 November 2009) Treatment of cystic fibrosis in a patient less than 5 years of age who initiated treatment with dornase alfa prior to 1 November 2009 and for whom a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team, documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Further reassessments are to be undertaken and documented yearly. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3347
Doxorubicin - Pegylated Liposomal	C1828		Where the patient is receiving treatment at/from a private hospital Treatment of acquired immunodeficiency syndrome-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement	Compliance with Written or Telephone Authority Required procedures

	C1829		Where the patient is receiving treatment at/from a private hospital Treatment of acquired immunodeficiency syndrome-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement	Compliance with Written or Telephone Authority Required procedures
	C3348		Where the patient is receiving treatment at/from a public hospital Treatment of acquired immunodeficiency syndrome-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3348
	C3349		Where the patient is receiving treatment at/from a public hospital Treatment of acquired immunodeficiency syndrome-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3349
Efavirenz	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Emtricitabine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures

	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Enfuvirtide	C2007		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus (HIV) infection in antiretroviral experienced patients with treatment failure characterised by evidence of HIV replication despite ongoing therapy; and where the patient has failed previous treatment with 3 different antiretroviral regimens; and where the patient's previous treatment has included at least 1 non-nucleoside reverse transcriptase inhibitor, at least 1 nucleoside reverse transcriptase inhibitor and at least 1 protease inhibitor	Compliance with Written or Telephone Authority Required procedures
	C2008		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus (HIV) infection in antiretroviral experienced patients with treatment failure characterised by treatment-limiting toxicity to previous antiretroviral agents; and where the patient has failed previous treatment with 3 different antiretroviral regimens; and where the patient's previous treatment has included at least 1 non-nucleoside reverse transcriptase inhibitor, at least 1 nucleoside reverse transcriptase inhibitor and at least 1 protease inhibitor	Compliance with Written or Telephone Authority Required procedures
	C3350		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus (HIV) infection in antiretroviral experienced patients with treatment failure characterised by evidence of HIV replication despite ongoing therapy; and where the patient has failed previous treatment with 3 different antiretroviral regimens; and where the patient's previous treatment has included at least 1 non-nucleoside reverse transcriptase inhibitor, at least 1 nucleoside reverse transcriptase inhibitor and at least 1 protease inhibitor	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3350
	C3351		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus (HIV) infection in antiretroviral experienced patients with treatment failure characterised by treatment-limiting toxicity to previous antiretroviral agents; and where the patient has failed previous treatment with 3 different antiretroviral regimens; and where the patient's previous treatment has included at least 1 non-nucleoside reverse transcriptase inhibitor, at least 1 nucleoside reverse transcriptase inhibitor and at least 1 protease inhibitor	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3351

Entecavir	C2935		Where the patient is receiving treatment at/from a private hospital Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria: (1)(a) 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 (b) 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 (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures
	C2937		Where the patient is receiving treatment at/from a private hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy) (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures
	C3352		Where the patient is receiving treatment at/from a public hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3352

	C3353		Where the patient is receiving treatment at/from a public hospital Patients with chronic hepatitis B who have failed lamivudine therapy and who satisfy all of the following criteria: (1)(a) 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 (b) 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; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3353
Epoetin Alfa	C1957		Where the patient is receiving treatment at/from a private hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.	Compliance with Written or Telephone Authority Required procedures
	C3334		Where the patient is receiving treatment at/from a public hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3334
Epoetin Beta	C1957		Where the patient is receiving treatment at/from a private hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.	Compliance with Written or Telephone Authority Required procedures
	C3334		Where the patient is receiving treatment at/from a public hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3334
Epoetin Lambda	C1957		Where the patient is receiving treatment at/from a private hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.	Compliance with Written or Telephone Authority Required procedures
	C3334		Where the patient is receiving treatment at/from a public hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3334

Epoprostenol			**Definitions** For the purpose of PBS-subsidised supply of epoprostenol for C3163, C3164, C3165, C3166 and C3167: ***"PAH agent"*** means ambrisentan, bosentan, epoprostenol, iloprost, sildenafil or sitaxentan ***"Primary pulmonary hypertension"*** means: (i) pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or (iii) where right heart catheterisation cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function ***"Response to epoprostenol or prior vasodilator treatment"*** means: (i) for adult patients with 2 or more baseline tests – as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (ii) for adult patients with an RHC composite assessment alone at baseline – as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iii) for adult patients with an ECHO composite assessment alone at baseline – as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iv) for patients aged less than 18 years – as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital	
	C3163		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (new adult patients) Initial PBS-subsidised treatment with epoprostenol sodium of adult patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have World Health Organisation (WHO) Functional Class IV primary pulmonary hypertension; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and	Compliance with modified Authority Required procedures

			(3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3164		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (new patients under 18 years of age) Initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have World Health Organisation (WHO) Functional Class IV primary pulmonary hypertension; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a patient acknowledgment, signed by the parent or authorised guardian and the prescriber, indicating that they understand and acknowledge that PBS-subsidised treatment with PAH agents will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures
	C3165		Where the patient is receiving treatment at/from a private or public hospital Initial treatment	Compliance with modified Authority Required

			(change or re-commencement for all adult patients) Initial PBS-subsidised treatment with epoprostenol sodium of adult patients: (a) who have primary pulmonary hypertension, who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; or (b) who have World Health Organisation (WHO) Functional Class IV primary pulmonary hypertension and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; or (c) who have WHO Functional Class III primary pulmonary hypertension and who have failed to respond to a prior PBS-subsidised PAH agent; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to; and (5) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	procedures
	C3166		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for all patients under 18 years of age) Initial PBS-subsidised treatment with epoprostenol sodium of patients aged less than 18 years: (a) who have primary pulmonary hypertension, who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; or (b) who have World Health Organisation (WHO) Functional Class IV primary pulmonary hypertension and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; or (c) who have WHO Functional Class III primary pulmonary hypertension and who have failed to respond to a prior PBS-subsidised PAH agent; and where the following conditions apply: the authority application is made in writing and includes:	Compliance with modified Authority Required procedures

			(1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to; and. (5) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3167		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment (all patients) Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that the test results included in the application are from the same tests as were conducted at baseline, except for patients who were able to undergo all 3 tests at baseline and whose subsequent ECHO composite assessment and 6MWT results demonstrate disease stability or improvement, in which case RHC composite assessment can be omitted: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) ECHO composite assessment plus 6MWT; or (iv) RHC composite assessment alone; or (v) ECHO composite assessment alone; and (2) where the same test or tests conducted at baseline cannot be performed on clinical grounds for assessment of response, a patient specific reason why the test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be	Compliance with modified Authority Required procedures

			submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
Etanercept	C3531		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — initial treatment 1 (new patient or patient recommencing after a break of more than 12 months) Initial treatment commencing a treatment cycle, by a paediatric rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years: (a) who has severe active juvenile idiopathic arthritis; and (b) whose parent or authorised guardian has signed a patient acknowledgement; and (c) who has not received PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 12 months; and (d) who has demonstrated either: (i) severe intolerance of, or toxicity due to, methotrexate; or (ii) failure to achieve an adequate response to 1 or more of the following treatment regimens: — 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 — 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 where bDMARD means adalimumab or etanercept; and where the following conditions apply: severe intolerance is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs 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 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 Therapeutic Goods Administration-approved Product Information, the authority application provides details of the contraindication; if intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, the authority application provides details of this toxicity; failure to achieve an adequate response is indicated by the following criteria and must be demonstrated in all patients at the time of the authority 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 active if swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as active if there is 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 is performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form and an acknowledgement signed by a parent or authorised guardian; a patient whose previous treatment cycle was ceased due to their failure to respond to bDMARD treatment 3 times (twice with one agent and once with the other) is eligible to commence a new treatment cycle with an initial course of etanercept provided a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the	Compliance with modified Authority Required procedures

			date of the first application under the new treatment cycle; a course of initial treatment commencing a treatment cycle is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	
	C3532		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — initial treatment 2 (change or recommencement after a break of less than 12 months) Initial PBS-subsidised treatment, or recommencement of treatment, with etanercept within an ongoing treatment cycle, by a paediatric rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who: (a) has a documented history of severe active juvenile idiopathic arthritis; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or etanercept for this condition; and (c) has not failed PBS-subsidised therapy with etanercept for this condition more than once in the current treatment cycle; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with etanercept in this treatment cycle and wishes to recommence therapy with this drug, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised etanercept treatment is a 16 week initial treatment course, is made following a minimum of 12 weeks of therapy; a patient who has failed to respond to treatment with adalimumab and etanercept 3 times (twice with one agent and once with the other) is not eligible to receive further PBS-subsidised therapy in this treatment cycle; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	Compliance with modified Authority Required procedures
	C3533		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — continuing treatment Continuing PBS-subsidised treatment with etanercept within an ongoing treatment cycle, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient: (a) who has a documented history of severe active juvenile idiopathic arthritis; and (b) who has demonstrated an adequate response to treatment with etanercept; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle was with etanercept; and where bDMARD means adalimumab or etanercept; and where the following conditions apply: an adequate response to treatment is defined as: (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 joints which are active, from at least 4, by at least 50%:	Compliance with modified Authority Required procedures

			— elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder, cervical spine and/or hip (assessed as active if there is 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 joints assessed to establish baseline joint count at the commencement of an initial course of treatment are assessed to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with etanercept; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of etanercept therapy is a 16 week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a patient who has failed to respond to bDMARD treatment 3 times (twice with one agent and once with the other) is not eligible to receive further PBS-subsidised therapy in this treatment cycle; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
	C3534		Where the patient is receiving treatment at/from a private or public hospital Juvenile idiopathic arthritis — continuing treatment (patient 18 years or older) Continuing PBS-subsidised treatment with etanercept within an ongoing treatment cycle, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient 18 years or older: (a) who has a documented history of severe active juvenile idiopathic arthritis; and (b) who has demonstrated an adequate response to treatment with etanercept; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle was with etanercept; and where bDMARD means adalimumab or etanercept; and where the following conditions apply: an adequate response to treatment is defined as: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder, cervical spine and/or hip (assessed as active if there is 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 joints assessed to establish baseline joint count at the commencement of an initial course of treatment are assessed to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with etanercept; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from	Compliance with modified Authority Required procedures

			the cessation of the treatment course; if the most recent course of etanercept therapy is a 16 week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a patient who has failed to respond to bDMARD treatment 3 times (twice with one agent and once with the other) is not eligible to receive further PBS-subsidised therapy in this treatment cycle; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
Etravirine	C2956		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus (HIV) infection in an antiretroviral experienced patient with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included: (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and (ii) at least 1 nucleoside reverse transcriptase inhibitor; and (iii) at least 1 protease inhibitor	Compliance with Written or Telephone Authority Required procedures
	C3354		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus (HIV) infection in an antiretroviral experienced patient with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included: (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and (ii) at least 1 nucleoside reverse transcriptase inhibitor; and (iii) at least 1 protease inhibitor	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3354
Everolimus	C1650		Where the patient is receiving treatment at/from a private hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C1651		Where the patient is receiving treatment at/from a private hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures

	C3355		Where the patient is receiving treatment at/from a public hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3355
	C3356		Where the patient is receiving treatment at/from a public hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3356
Filgrastim	C2912		Where the patient is receiving treatment at/from a private hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;	Compliance with Written or Telephone Authority Required procedures
	C2913		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy;	Compliance with Written or Telephone Authority Required procedures
	C2914		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation;	Compliance with Written or Telephone Authority Required procedures
	C2915		Where the patient is receiving treatment at/from a private hospital A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation;	Compliance with Written or Telephone Authority Required procedures
	C2916		Where the patient is receiving treatment at/from a private hospital A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation;	Compliance with Written or Telephone Authority Required procedures
	C2917		Where the patient is receiving treatment at/from a private hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2918		Where the patient is receiving treatment at/from a private hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures

	C2919		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2920		Where the patient is receiving treatment at/from a private hospital A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage);	Compliance with Written or Telephone Authority Required procedures
	C2921		Where the patient is receiving treatment at/from a private hospital A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));	Compliance with Written or Telephone Authority Required procedures
	C2922		Where the patient is receiving treatment at/from a private hospital A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months));	Compliance with Written or Telephone Authority Required procedures
	C2923		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures
	C2924		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures
	C2925		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures
	C2926		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures
	C2927		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures
	C2928		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures

	C2929		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures
	C2930		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures
	C3087		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C3187		Where the patient is receiving treatment at/from a private hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.	Compliance with Written or Telephone Authority Required procedures
	C3357		Where the patient is receiving treatment at/from a public hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3357
	C3358		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3358
	C3359		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3359

	C3360		Where the patient is receiving treatment at/from a public hospital A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3360
	C3361		Where the patient is receiving treatment at/from a public hospital A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3361
	C3362		Where the patient is receiving treatment at/from a public hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3362
	C3363		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3363
	C3364		Where the patient is receiving treatment at/from a public hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3364
	C3365		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3365

	C3366		Where the patient is receiving treatment at/from a public hospital A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3366
	C3367		Where the patient is receiving treatment at/from a public hospital A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3367
	C3368		Where the patient is receiving treatment at/from a public hospital A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3368
	C3369		Where the patient is receiving treatment at/from a public hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3369
	C3370		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3370
	C3371		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3371

	C3372		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3372
	C3373		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3373
	C3374		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3374
	C3375		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3375
	C3376		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3376
	C3377		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3377
Fosamprenavir	C1832		Where the patient is receiving treatment at/from a private hospital	Compliance with Written or

			Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Telephone Authority Required procedures
	C1833		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3315		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3315
	C3316		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3316
Foscarnet	C1413		Where the patient is receiving treatment at/from a private hospital Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with human immunodeficiency virus infection	Compliance with Written or Telephone Authority Required procedures
	C1610		Where the patient is receiving treatment at/from a private hospital Treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome	Compliance with Written or Telephone Authority Required procedures
	C3322		Where the patient is receiving treatment at/from a public hospital Treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3322
	C3378		Where the patient is receiving treatment at/from a public hospital Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with human immunodeficiency virus infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3378
Ganciclovir	C1612		Where the patient is receiving treatment at/from a private hospital	Compliance with Written or Telephone Authority

			Cytomegalovirus retinitis in severely immunocompromised patients;	Required procedures
	C1830		Where the patient is receiving treatment at/from a private hospital Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease;	Compliance with Written or Telephone Authority Required procedures
	C1831		Where the patient is receiving treatment at/from a private hospital Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease.	Compliance with Written or Telephone Authority Required procedures
	C3379		Where the patient is receiving treatment at/from a public hospital Cytomegalovirus retinitis in severely immunocompromised patients	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3379
	C3380		Where the patient is receiving treatment at/from a public hospital Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3380
	C3381		Where the patient is receiving treatment at/from a public hospital Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3381
Ibandronic acid	C1035		Where the patient is receiving treatment at/from a private hospital Bone metastases from breast cancer.	Compliance with Written or Telephone Authority Required procedures
	C3343		Where the patient is receiving treatment at/from a public hospital Bone metastases from breast cancer	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3343
Iloprost			**Definitions** For the purpose of PBS-subsidised supply of iloprost for C3168, C 3169, C3170 and C3171:	

			"PAH agent" means ambrisentan, bosentan, epoprostenol, iloprost, sildenafil or sitaxentan ***"Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension and pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma"*** means: (i) pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or (iii) where right heart catheterisation cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function ***"Response to iloprost or prior vasodilator treatment"*** means: (i) for adult patients with 2 or more baseline tests – as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (ii) for adult patients with an RHC composite assessment alone at baseline – as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iii) for adult patients with an ECHO composite assessment alone at baseline – as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iv) for patients aged less than 18 years – as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital	
	C3168		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 1 (new patients) Initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with iloprost, who have been assessed by a physician from a designated hospital to have World Health Organisation (WHO) Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO), and who have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; and: where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a	Compliance with modified Authority Required procedures

			response to treatment; and (3) details of prior vasodilator treatment, including the dose and duration of treatment; and (4) where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information, details on the nature of the adverse event or contraindication; and (5) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3169		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 2 (new patients) Initial PBS-subsidised treatment with iloprost trometamol of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III drug-induced pulmonary arterial hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds; right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class IV primary pulmonary hypertension; or (c) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; or (d) WHO Functional Class IV drug-induced pulmonary arterial hypertension; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and	Compliance with modified Authority Required procedures

			(3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3170		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for all patients) Initial PBS-subsidised treatment with iloprost trometamol of patients: (a) who have primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, who wish to re-commence PBS-subsidised iloprost trometamol after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with iloprost trometamol; or (b) who have World Health Organisation (WHO) Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than iloprost trometamol; or (c) who have WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) for WHO Functional Class III patients, where this is the first application for iloprost trometamol, assessment details of the PBS-subsidised PAH agent they have failed to respond to; and. (5) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures
	C3171		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment	Compliance with modified Authority Required

			(all patients) Continuing PBS-subsidised treatment with iloprost trometamol of patients who have received approval for initial PBS-subsidised treatment with iloprost trometamol and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of iloprost trometamol treatment; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that the test results included in the application are from the same tests as were conducted at baseline, except for patients who were able to undergo all 3 tests at baseline and whose subsequent ECHO composite assessment and 6MWT results demonstrate disease stability or improvement, in which case RHC composite assessment can be omitted: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) ECHO composite assessment plus 6MWT; or (iv) RHC composite assessment alone; or (v) ECHO composite assessment alone; and (2) where the same test or tests conducted at baseline cannot be performed on clinical grounds for assessment of response, a patient specific reason why the test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	procedures
Indinavir	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital	Compliance with Written or

			Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Telephone Authority Required procedures - Streamlined Authority Code 3310
Infliximab	C2996		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 1 (adult patient assessed by CDAI) Initial treatment commencing a treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with severe refractory Crohn disease who satisfies the following criteria: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) has not received any prior PBS-subsidised treatment with adalimumab or infliximab for Crohn disease, or, where the patient has previously received PBS-subsidised treatment with adalimumab or infliximab for this condition, has received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised treatment with adalimumab or infliximab for this condition was approved; and (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) has failed to achieve an adequate response to prior systemic therapy including: (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and (ii) 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 15 mg weekly for 3 or more months; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens mentioned at (d) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; failure to achieve an adequate response is indicated by a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed, and is demonstrated in the patient at the time of the authority application; all tests and assessments are performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; the most recent CDAI assessment is no more than 1 month old at the time of application; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:	Compliance with modified Authority Required procedures

			(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy); and (iii) the signed patient acknowledgement; a course of initial treatment commencing a treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	
	C2997		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 2 (adult patient assessed by CDAI) Initial treatment, or recommencement of treatment, with infliximab within an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient who: (a) has a documented history of severe refractory Crohn disease; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the application for authorisation is made in writing and includes a completed copy of the appropriate 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 the assessment of the patient's condition; and (ii) details of prior adalimumab and infliximab treatment including details of date and duration of treatment; and to demonstrate a response to treatment the application is accompanied by the results of the patient's most recent course of adalimumab or infliximab therapy where: (a) the response assessment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course was ceased; and (b) (i) if the course of therapy is a 16-week initial course (in the case of adalimumab), the assessment of response is made following a minimum of 12 weeks of treatment; or (ii) if the course of therapy is a 3 dose initial course (in the case of infliximab), the assessment of response is made up to 12 weeks after the first dose (6 weeks following the third dose); if the response assessment to the previous course of adalimumab or infliximab treatment is not submitted as detailed above, the patient is deemed to have failed therapy with that particular course of treatment; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	Compliance with modified Authority Required procedures
	C2998		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — continuing treatment	Compliance with modified Authority Required

			(adult patient assessed by CDAI) Continuing treatment within an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; the CDAI assessment is no more than 1 month old at the time of application; the CDAI assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO as detailed above the patient is deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab, despite demonstrating a response as defined above; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response	procedures
	C2999		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 1 (adult patient - short gut syndrome or an ostomy patient) Initial treatment commencing a treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with severe refractory Crohn disease who satisfies the following criteria: (a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and (c) has evidence of intestinal inflammation; and (d) has not received any prior PBS-subsidised treatment with adalimumab or infliximab for Crohn disease, or, where the patient has previously received PBS-subsidised treatment with adalimumab or infliximab for this condition, has received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised treatment with adalimumab or infliximab for this condition was approved; and (e) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the	Compliance with modified Authority Required procedures

			restriction for continuing treatment; and (f) has failed to achieve an adequate response to prior systemic drug therapy including: (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and (ii) 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 15 mg weekly for 3 or more months; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: if treatment with any of the drugs mentioned at (f) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens mentioned at (f) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; failure to achieve an adequate response is indicated by the following and is demonstrated in the patient at the time of the authority application: (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; and/or (ii) faeces: higher than normal lactoferrin or calprotectin level; and/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; and/or (b) be assessed clinically as being in a high faecal output state; and/or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab; all tests and assessments are performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy); and (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) date of the most recent clinical assessment; and (iv) the signed patient acknowledgement; all assessments, pathology tests and diagnostic imaging studies are made within 1 month of the date of application; a course of initial treatment commencing a treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	
	C3000		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 2 (adult patient - short gut syndrome, extensive small intestine disease, or an ostomy patient) Initial treatment, or recommencement of treatment, with infliximab within an ongoing treatment cycle, by a gastroenterologist,	Compliance with modified Authority Required procedures

			a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient who: (a) has a documented history of severe refractory Crohn disease and has short gut syndrome, an ileostomy or colostomy, or extensive small intestine disease; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and (ii) details of prior adalimumab and infliximab treatment including details of date and duration of treatment; to demonstrate a response to treatment the application is accompanied by the results of the patient's most recent course of adalimumab or infliximab therapy where: (a) the response assessment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course was ceased; and (b) (i) if the course of therapy is a 16-week initial course (in the case of adalimumab), the assessment of response is made following a minimum of 12 weeks of treatment; or (ii) if the course of therapy is a 3 dose initial course (in the case of infliximab), the assessment of response is made up to 12 weeks after the first dose (6 weeks following the third dose); if the response assessment to the previous course of adalimumab or infliximab treatment is not submitted as detailed above, the patient is deemed to have failed therapy with that particular course of treatment; the same baseline criterion used to determine response to an initial course of infliximab treatment is used to determine response, and thus eligibility for continued PBS-subsidised therapy, to subsequent courses of treatment; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	
	C3001		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — continuing treatment (adult patient - short gut syndrome or an ostomy patient) Continuing treatment in an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with	Compliance with modified Authority Required procedures

			the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or 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; and/or (ii) faeces: normalisation of lactoferrin or calprotectin level; and/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); the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment; the patient's assessment is no more than 1 month old at the time of application; the assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO as detailed above the patient is deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab, despite demonstrating a response as defined above; the same baseline criterion used to determine response to an initial course of infliximab treatment is used to determine response, and thus eligibility for continued PBS-subsidised therapy, to subsequent courses of treatment; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response	
	C3002		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 1 (adult patient - extensive small intestine disease) Initial treatment commencing a treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with severe refractory Crohn disease who satisfies the following criteria: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and (c) has not received any prior PBS-subsidised treatment with adalimumab or infliximab for Crohn disease, or, where the patient has previously received PBS-subsidised treatment with adalimumab or infliximab for this condition, has received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised treatment with adalimumab or infliximab for this condition was approved; and (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (e) has failed to achieve an adequate response to prior systemic therapy including:	Compliance with modified Authority Required procedures

			(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and (ii) 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 15 mg weekly for 3 or more months; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: if treatment with any of the drugs mentioned at (e) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens mentioned at (e) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; failure to achieve an adequate response is indicated by the following and is demonstrated in the patient at the time of the authority application: (a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and/or (b) have evidence of active intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; and/or (ii) faeces: higher than normal lactoferrin or calprotectin level; and/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; and/or (c) be assessed clinically as being in a high faecal output state; and/or (d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab; all tests and assessments are performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy); and (ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and (iii) date of the most recent clinical assessment; and (iv) the signed patient acknowledgement; all assessments, pathology tests and diagnostic imaging studies are made within 1 month of the date of application; a course of initial treatment commencing a treatment cycle is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	
	C3003		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — continuing treatment	Compliance with modified Authority Required

			(adult patient - extensive small intestine disease) Continuing treatment in an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or (b) improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or 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; and/or (ii) faeces: normalisation of lactoferrin or calprotectin level; and/or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (c) reversal of high faecal output state; or (d) avoidance of the need for surgery or total parenteral nutrition (TPN); the application for authorisation is made in writing and includes a completed copy of the appropriate 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; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or (iii) the date of clinical assessment; all assessments are no more than 1 month old at the time of application; the assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO as detailed above the patient is deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab, despite demonstrating a response as defined above; the same baseline criterion used to determine response to an initial course of infliximab treatment is used to determine response, and thus eligibility for continued PBS-subsidised therapy, to subsequent courses of treatment; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response	procedures
	C3004		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 3 (adult patient assessed by CDAI)	Compliance with modified Authority Required procedures

			Commencement of a treatment cycle with an initial PBS-subsidised course of infliximab for continuing treatment, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and (b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and (ii) the signed patient acknowledgment; the current CDAI assessment is no more than 1 month old at the time of application; the baseline CDAI assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; a patient may qualify for PBS-subsidised treatment under this restriction once only	
	C3005		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment 3 (adult patient - short gut syndrome, extensive small intestine disease, or an ostomy patient) Commencement of a treatment cycle with an initial PBS-subsidised course of infliximab for continuing treatment, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and (b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or (2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment	Compliance with modified Authority Required procedures

			will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or (b) improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or 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; and/or (ii) faeces: normalisation of lactoferrin or calprotectin level; and/or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (c) reversal of high faecal output state; or (d) avoidance of the need for surgery or total parenteral nutrition (TPN); the same criteria used to determine an inadequate response to prior treatment at baseline are used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or (2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or (3) the date of clinical assessment(s); and (ii) the signed patient acknowledgement; the patient's assessment is no more than 1 month old at the time of application; the baseline assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; a patient may qualify for PBS-subsidised treatment under this restriction once only	

	C3006		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment (paediatric patient) Initial PBS-subsidised treatment by a gastroenterologist, paediatrician, consultant physician in internal medicine specialising in gastroenterology or consultant physician in general medicine specialising in gastroenterology, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if the patient does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (c) has 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 40 mg prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; (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; and where the following conditions apply: if treatment with any of the drugs mentioned at (c) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens mentioned at (c) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; failure to achieve an adequate response is indicated by severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment, and is demonstrated in the patient at the time of the authority application; the most recent PCDAI assessment is no more than 1 month old at the time of application; all tests and assessments are performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate 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; and (ii) details of previous systemic drug therapy (dosage, date of commencement and duration of therapy), or dates of enteral nutrition; and (iii) the signed patient acknowledgement; a course of initial treatment is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	Compliance with modified Authority Required procedures
	C3007		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — continuing treatment (patient initiated on PBS-subsidised treatment as a paediatric patient) Continuing PBS-subsidised treatment by a gastroenterologist, paediatrician, consultant physician in internal medicine specialising in gastroenterology, consultant physician in general medicine specialising in gastroenterology or other	Compliance with modified Authority Required procedures

			consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of moderate to severe refractory Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and (c) qualified for initial PBS-subsidised therapy as a paediatric patient aged from 6 to 17 years inclusive; and where the following conditions apply: an adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline and a total PCDAI score of 30 points or less; the application for authorisation is made in writing and includes a completed copy of the appropriate 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 is no more than 1 month old at the time of application; the PCDAI assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO as detailed above the patient is deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab, despite demonstrating a response as defined above; a course of continuing treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response; patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab are not eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased	
	C3008		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment (paediatric patient - previous treatment not PBS-subsidised) Initial PBS-subsidised supply for continuing treatment by a gastroenterologist, paediatrician, consultant physician in internal medicine specialising in gastroenterology, consultant physician in general medicine specialising in gastroenterology or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who: (a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and (b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab; and (c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the patient does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) has demonstrated or sustained an adequate response to treatment with infliximab; and where the following conditions apply: an adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline and a total PCDAI score of 30 points or less; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and	Compliance with modified Authority Required procedures

			(ii) the signed patient acknowledgement; the current PCDAI assessment is no more than 1 month old at the time of application; the baseline PCDAI assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, a subsequent authority application for a supply sufficient to enable the patient to complete a course of 24 weeks of therapy in total may be submitted by telephone; a patient may qualify for PBS-subsidised treatment under this restriction once only	
	C3259		Where the patient is receiving treatment at/from a private or public hospital Chronic plaque psoriasis (whole body) — initial treatment 1 Initial treatment as systemic monotherapy (other than methotrexate), commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who: (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has received prior PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more, starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment of psoriasis affecting the whole body; and (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to at least 1 of the 4 treatments, for a minimum of 6 weeks; and where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response is indicated by 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, and is demonstrated in the patient at the time of the authority application; a PASI assessment is completed for each prior treatment course, preferably whilst still on treatment but no longer than 1 month following cessation of each course of treatment; the most recent PASI assessment is no more than 1 month old at the time of application; if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or phototherapy is contraindicated, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (d) above develops during the relevant period of use and is of a	Compliance with modified Authority Required procedures

			severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the application for authorisation is made in writing and includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and (iii) the signed patient and prescriber acknowledgements; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
	C3260		Where the patient is receiving treatment at/from a private or public hospital Chronic plaque psoriasis (whole body) — initial treatment 2 Initial treatment, or recommencement of treatment, with infliximab as systemic monotherapy (other than methotrexate), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who: (a) have a documented history of severe chronic plaque psoriasis; and (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and (c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle; and where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who have previously demonstrated a response to PBS-subsidised treatment with infliximab within this Treatment Cycle are only eligible to recommence therapy with this drug within this same cycle, following a break in therapy, where evidence of a response to their most recent course of PBS-subsidised infliximab treatment was submitted to the Medicare Australia CEO within 1 month of cessation of that treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate 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 agent treatment, including dosage, date and duration of treatment; a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	Compliance with modified Authority Required procedures
	C3261		Where the patient is receiving treatment at/from a private or public hospital Chronic plaque psoriasis (whole body) — continuing treatment Continuing treatment as systemic monotherapy (other than methotrexate), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over: (a) who have a documented history of severe chronic plaque psoriasis; and	Compliance with modified Authority Required procedures

			(b) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle was with infliximab; and (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab; and where biological agent means adalimimab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as a Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle; the PASI assessment submitted to demonstrate response is performed on the same affected body area assessed to establish the baseline value; the PASI assessment of response is made after at least 12 weeks of treatment, in the case of a 22-week initial treatment course, or is conducted within 4 weeks prior to completion of the course, in the case of a 24-week treatment course, and is submitted to the Medicare Australia CEO no later than 1 month from the date of completion of the course of treatment; where an assessment of the patient's response to a course of PBS-subsidised treatment is not undertaken and submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed to respond to treatment with infliximab; the application for authorisation is made in writing and includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition; the most recent PASI assessment is no more than 1 month old at the time of application; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
	C3262		Where the patient is receiving treatment at/from a private or public hospital Chronic plaque psoriasis (face, hand, foot) — initial treatment 1 Initial treatment as systemic monotherapy (other than methotrexate), commencing a Biological Treatment Cycle, by a dermatologist for adults 18 years and over who: (a) 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 (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has received prior PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more, starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment of psoriasis affecting the face, hand or foot; and (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or	Compliance with modified Authority Required procedures

			(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; unless the patient has had a break in PBS-subsidised biological agent treatment of at least 5 years, in which case the patient is required to demonstrate failure to achieve an adequate response to at least 1 of the 4 treatments, for a minimum of 6 weeks; and where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response is demonstrated in the patient at the time of the authority application and is indicated by 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; a PASI assessment is completed for each prior treatment course, preferably whilst still on treatment but no longer than 1 month following cessation of each course of treatment; the most recent PASI assessment is no more than 1 month old at the time of application; if treatment with any of the drugs mentioned at (d) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, or phototherapy is contraindicated, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (d) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the application for authorisation is made in writing and includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and (iii) the signed patient and prescriber acknowledgements; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
	C3263		Where the patient is receiving treatment at/from a private or public hospital Chronic plaque psoriasis (face, hand, foot) — initial treatment 2 Initial treatment, or recommencement of treatment, with infliximab as systemic monotherapy (other than methotrexate), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over who: (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and	Compliance with modified Authority Required procedures

			(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle; and where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients who have previously demonstrated a response to PBS-subsidised treatment with infliximab within this Treatment Cycle are only eligible to recommence therapy with this drug within this same cycle, following a break in therapy, where evidence of a response to their most recent course of PBS-subsidised infliximab treatment was submitted to the Medicare Australia CEO within 1 month of cessation of that treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate 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 agent treatment, including dosage, date and duration of treatment; a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
	C3264		Where the patient is receiving treatment at/from a private or public hospital Chronic plaque psoriasis (face, hand, foot) — continuing treatment Continuing treatment as systemic monotherapy (other than methotrexate), within an ongoing Biological Treatment Cycle, by a dermatologist for adults 18 years and over: (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and (b) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle was with infliximab; and (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab; and where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological agent treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value; the PASI assessment submitted to demonstrate response is performed on the same affected body area assessed to establish the baseline value; the PASI assessment of response is made after at least 12 weeks of treatment, in the case of a 22-week initial treatment	Compliance with modified Authority Required procedures

			course, or is conducted within 4 weeks prior to completion of the course, in the case of a 24-week treatment course, and is submitted to the Medicare Australia CEO no later than 1 month from the date of completion of the course of treatment; where an assessment of the patient's response to a course of PBS-subsidised treatment is not undertaken and submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed to respond to treatment with infliximab; the application for authorisation is made in writing and includes a completed copy of the appropriate 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 along with the date of the assessment of the patient's condition; the most recent PASI assessment is not more than 1 month old at the time of application; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
	C3452		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment Initial PBS-subsidised treatment with infliximab, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) has an externally draining enterocutaneous or rectovaginal fistula; and (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the most recent fistula assessment is no more than 1 month old at the time of application; a course of initial treatment is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone	Compliance with modified Authority Required procedures
	C3453		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — recommencement of PBS-subsidised treatment Re-initiation of PBS-subsidised treatment of complex refractory fistulising Crohn disease, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has an externally draining enterocutaneous or rectovaginal fistula; and (c) has previously received PBS-subsidised infliximab treatment for a draining enterocutaneous or rectovaginal fistula; and (d) either: (i) has demonstrated or sustained an adequate response to the most recent course of PBS-subsidised treatment with	Compliance with modified Authority Required procedures

			infliximab for this condition; or (ii) has failed to demonstrate or sustain an adequate response to PBS-subsidised treatment with infliximab for this condition and 12 months have elapsed from the date on which treatment was ceased; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition; the most recent fistula assessment is no more than 1 month old at the time of application; a course re-initiating PBS-subsidised treatment is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone; a patient who fails to respond to a course of PBS-subsidised infliximab for the treatment of complex refractory fistulising Crohn disease is not eligible to receive further PBS-subsidised treatment with infliximab for this condition within 12 months of the date on which treatment was ceased	
	C3454		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial PBS-subsidised treatment (previous infliximab treatment non-PBS-subsidised) Initial PBS-subsidised supply for continuing treatment with infliximab, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who satisfies the following criteria: (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) is receiving treatment with infliximab at the time of application; and (e) has demonstrated or sustained an adequate response to treatment with infliximab; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the application for authorisation is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the current fistula assessment is no more than 1 month old at the time of application; the baseline fistula assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; a patient is eligible for PBS-subsidised treatment under this restriction once only	Compliance with modified Authority Required procedures

	C3455		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — continuing treatment Continuing PBS-subsidised treatment with infliximab, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where the following conditions apply: an adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition; the fistula assessment is no more than 1 month old at the time of application; the assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (up to 6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab; a course of continuing treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response	Compliance with modified Authority Required procedures
	C3492		Where the patient is receiving treatment at/from a private or public hospital Psoriatic arthritis — initial treatment 1 Initial treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have severe active psoriatic arthritis; and (2) have received no prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has previously received PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (3) 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 to either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; and where biological agent means adalimumab, etanercept, golimumab or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply:	Compliance with modified Authority Required procedures

			failure to achieve an adequate response to the treatment regimens specified at (3) above is demonstrated by the following: (a) 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 (b) either: (i) an active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; if treatment with any of the drugs mentioned at (3) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (3) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgment; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
	C3493		Where the patient is receiving treatment at/from a private or public hospital Psoriatic arthritis — initial treatment 2 Initial treatment, or recommencement of treatment, with infliximab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have a documented history of severe active psoriatic arthritis; and (2) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle and are eligible to receive further therapy with a biological agent; and (3) have not failed treatment with infliximab during the current Treatment Cycle; and where biological agent means adalimumab, etanercept, golimumab or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients are eligible to receive further therapy with a biological agent within this Treatment Cycle provided they have not already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with infliximab within this Treatment Cycle and wishes to recommence therapy with this drug within this same cycle, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised infliximab treatment is a 22-week	Compliance with modified Authority Required procedures

			initial treatment course, is made following a minimum of 12 weeks of therapy; a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
	C3494		Where the patient is receiving treatment at/from a private or public hospital Psoriatic arthritis — continuing treatment Continuing treatment with infliximab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults: (1) who have a documented history of severe active psoriatic arthritis; and (2) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle was with infliximab; and (3) who, at the time of application, demonstrate an adequate response to treatment with infliximab; and where biological agent means adalimumab, etanercept, golimumab or infliximab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for psoriatic arthritis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to treatment with infliximab is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and 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 an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with infliximab; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of infliximab therapy is a 22-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	Compliance with modified Authority Required procedures

	C3513		Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis — initial treatment 1 Initial treatment with infliximab commencing a treatment cycle, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, and: (a) who has not received any PBS-subsidised treatment with a tumour necrosis factor (TNF)-alfa antagonist, or, where the patient has previously received PBS-subsidised TNF-alfa antagonist treatment for this condition, has received no such treatment for a period of 5 years or more starting from the date the last course of PBS-subsidised treatment was approved; and (b) who has 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 (c) who has 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 at least 3 months, unless the patient has had a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years duration, in which case the patient is required to demonstrate failure to achieve an adequate response to treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months; and where TNF-alfa antagonist means adalimumab, etanercept, golimumab or infliximab; and where a treatment cycle is a period of treatment with successive TNF-alfa antagonists which commences when an eligible patient (one who has not received PBS-subsidised treatment with a TNF-alfa antagonist for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 TNF-alfa antagonist, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised treatment with 3 TNF-alfa antagonists, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: failure to achieve an adequate response is demonstrated by: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale, where the BASDAI score is determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment, and is no more than 1 month old at the time of application; 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; both ESR and CRP measurements are included in the authority application and are no more than 1 month old; if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reason why this criterion cannot be satisfied; the authority application includes 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 Therapeutic Goods Administration (TGA)-approved Product Information, the authority application includes the reason why a higher dose cannot be used; if treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the authority application includes details of the contraindication; if intolerance to NSAID treatment develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the nature and severity of this intolerance; an appropriate minimum exercise program includes stretch and range of motion exercises at least 5 times per week, and either aerobic exercise of at least 20 minutes duration at least 3 times per week or a group exercise class at least once per week; if a patient is unable to complete the minimum exercise program, the authority application includes the clinical reasons for	Compliance with modified Authority Required procedures

			this and details what, if any, exercise program has been followed; the authority application is made in writing and includes a completed copy of the appropriate 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 signed patient acknowledgment form; and (iv) a completed Exercise Program Self Certification Form detailing the program followed and the dates over which it was followed, and including confirmation by the prescribing doctor that, to the best of their knowledge, the patient has followed the exercise program detailed; a course of initial treatment commencing a treatment cycle is limited to a maximum of 18 weeks of treatment; if less than 18 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 18 weeks of treatment in total may be submitted by telephone	
	C3514		Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis — initial treatment 2 Initial treatment, or recommencement of treatment, with infliximab within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised tumour necrosis factor (TNF)-alfa antagonist treatment for this condition and is eligible to receive further TNF-alfa antagonist therapy, and has not failed PBS-subsidised therapy with infliximab in the current treatment cycle; and where TNF-alfa antagonist means adalimumab, etanercept, golimumab or infliximab; and where a treatment cycle is a period of treatment with successive TNF-alfa antagonists which commences when an eligible patient (one who has not received PBS-subsidised treatment with a TNF-alfa antagonist for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 TNF-alfa antagonist, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised treatment with 3 TNF-alfa antagonists, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: a patient is eligible to receive further therapy with a TNF-alfa antagonist within this treatment cycle provided they have not already failed, or ceased to respond to, PBS-subsidised treatment with 3 TNF-alfa antagonists within this treatment cycle; the authority application is made in writing and includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form; an assessment of response to the patient's most recent course of PBS-subsidised TNF-alfa antagonist treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date that course was ceased; where the most recent course of TNF-antagonist treatment is an initial treatment course, the assessment of response is made following a minimum of 12 weeks of treatment; if the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of initial treatment within an ongoing treatment cycle is limited to a maximum of 18 weeks of treatment; if less than 18 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 18 weeks of treatment in total may be submitted by telephone	Compliance with modified Authority Required procedures
	C3515		Where the patient is receiving treatment at/from a private or public hospital Ankylosing spondylitis — continuing treatment Continuing treatment with infliximab within an ongoing treatment cycle, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has demonstrated an adequate response to treatment with infliximab, and whose most recent course of PBS-subsidised therapy in this treatment cycle was with infliximab; and	Compliance with modified Authority Required procedures

			where TNF-alfa antagonist means adalimumab, etanercept, golimumab or infliximab; and where a treatment cycle is a period of treatment with successive TNF-alfa antagonists which commences when an eligible patient (one who has not received PBS-subsidised treatment with a TNF-alfa antagonist for ankylosing spondylitis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 TNF-alfa antagonist, and which continues until the patient has tried and either failed, or ceased to respond to, PBS-subsidised treatment with 3 TNF-alfa antagonists, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response is defined as an improvement from baseline of at least 2 in the patient's Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and 1 of the following: (a) an erythrocyte sedimentation rate (ESR) measurement no greater than 25 mm per hour; or (b) a C-reactive protein (CRP) measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline; all measurements provided are no more than 1 month old at the time of application; where only 1 acute phase reactant measurement is supplied to establish baseline in the first application for PBS-subsidised treatment, that same marker is measured and supplied in all subsequent continuing treatment applications; the authority application is made in writing and includes a completed copy of the appropriate Ankylosing Spondylitis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with infliximab; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of infliximab therapy is an 18-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
	C3571		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 2 (change or recommencement after a break of less than 12 months) Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have a documented history of severe active rheumatoid arthritis; and (b) have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition within the previous 12 months and are eligible to receive further bDMARD therapy; and (c) have not failed previous PBS-subsidised treatment with infliximab for this condition; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: patients are eligible to receive further bDMARD therapy for rheumatoid arthritis provided they have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; patients who demonstrate a response to a course of PBS-subsidised treatment with rituximab and who wish to transfer to treatment with infliximab are not eligible to commence treatment with infliximab until they have completed a period free from PBS-subsidised bDMARD treatment of at least 22 weeks duration, immediately following the second rituximab infusion; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS	Compliance with modified Authority Required procedures

			Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with infliximab and wishes to recommence therapy with this drug, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised infliximab treatment is a 22-week initial treatment course, is made following a minimum of 12 weeks of therapy; a course of initial treatment is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
	C3572		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — continuing treatment Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with infliximab; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment was with infliximab; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: an adequate response to treatment is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and 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 an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with infliximab; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of infliximab therapy is a 22-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for	Compliance with modified Authority Required procedures

			supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
	C3581		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 1 (new patient or patient recommencing after a break of more than 12 months) Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have severe active rheumatoid arthritis; and (b) have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 12 months; and (c) have failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include: (i) 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: — hydroxychloroquine at a dose of at least 200 mg daily; or — leflunomide at a dose of at least 10 mg daily; or — sulfasalazine at a dose of at least 2 g daily; or (ii) if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose — at least 3 months continuous treatment with each of at least 2 of the following DMARDs: — hydroxychloroquine at a dose of at least 200 mg daily; and/or — leflunomide at a dose of at least 10 mg daily; and/or — sulfasalazine at a dose of at least 2 g daily; or (iii) 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 — at least 3 months continuous treatment with each of at least 2 DMARDs, one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: — azathioprine at a dose of at least 1 mg/kg per day; and/or — cyclosporin at a dose of at least 2 mg/kg/day; and/or — sodium aurothiomalate at a dose of 50 mg weekly; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, infliximab, golimumab, rituximab or tocilizumab; and where the following conditions apply: if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the authority application includes details of the contraindication or intolerance to methotrexate, and documents the maximum tolerated dose of methotrexate, if applicable; the authority application includes 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, the authority application provides details of the contraindication or intolerance and dose for each DMARD; failure to achieve an adequate response to the DMARD treatment specified above is demonstrated by the following: (a) 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	Compliance with modified Authority Required procedures

			(b) either: (i) a total active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is 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 are determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy, and all measures are 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 authority application states the reason this criterion cannot be satisfied; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgement; a patient is eligible for treatment if they have not failed previous PBS-subsidised treatment with infliximab for rheumatoid arthritis, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; a course of initial treatment is limited to a maximum of 22 weeks of treatment; if less than 22 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 22 weeks of treatment in total may be submitted by telephone	
Interferon Alfa-2a	C1463		Where the patient is receiving treatment at/from a private hospital Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;	Compliance with Written or Telephone Authority Required procedures
	C2939		Where the patient is receiving treatment at/from a private hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L); (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.	Compliance with Written or Telephone Authority Required procedures
	C3382		Where the patient is receiving treatment at/from a public hospital Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3382
	C3383		Where the patient is receiving treatment at/from a public hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3383

			(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L); (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception	
Interferon Alfa-2b	C1009		Where the patient is receiving treatment at/from a private hospital Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement;	Compliance with Written or Telephone Authority Required procedures
	C1463		Where the patient is receiving treatment at/from a private hospital Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase;	Compliance with Written or Telephone Authority Required procedures
	C2939		Where the patient is receiving treatment at/from a private hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L); (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.	Compliance with Written or Telephone Authority Required procedures
	C3382		Where the patient is receiving treatment at/from a public hospital Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3382
	C3383		Where the patient is receiving treatment at/from a public hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L); (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3383
	C3384		Where the patient is receiving treatment at/from a public hospital Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code

				3384
Interferon Gamma-1b	C1058		Where the patient is receiving treatment at/from a private hospital Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.	Compliance with Written or Telephone Authority Required procedures
	C3385		Where the patient is receiving treatment at/from a public hospital Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3385
Lamivudine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C2932		Where the patient is receiving treatment at/from a private hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310

	C3386		Where the patient is receiving treatment at/from a public hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3386
Lamivudine with Zidovudine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Lanreotide	C2619		Where the patient is receiving treatment at/from a private hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2	Compliance with Written or Telephone Authority Required procedures

			years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment	
	C2620		Where the patient is receiving treatment at/from a private hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment	Compliance with Written or Telephone Authority Required procedures
	C2621		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures
	C3387		Where the patient is receiving treatment at/from a public hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3387
	C3388		Where the patient is receiving treatment at/from a public hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3388

	C3389		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour Functional carcinoid tumour causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3389
Lanthanum	C3103		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures
	C3104		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures
	C3390		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3390
	C3391		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3391
Lenalidomide	C3204		Where the patient is receiving treatment at/from a private or public hospital Initial PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of a patient with a histological diagnosis of multiple myeloma who has progressive disease after at least 1 prior therapy, who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least 4 weeks of thalidomide at a dose of at least 100 mg daily or who has failed to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease; and where progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or	Compliance with modified Authority Required procedures

			(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); where oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria; where thalidomide treatment failure is defined as: (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment; where severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living; where toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity; where failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as: (1) less than a 25% reduction in serum or urine M protein; or (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels; and where the following conditions apply: the patient is not receiving concomitant PBS-subsidised bortezomib; the authority application is made in writing and includes: (1) a completed copy of the appropriate Multiple Myeloma Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and (2) duration of thalidomide and daily dose prescribed; and (3) a signed patient acknowledgment; if the dosing requirement for thalidomide cannot be met, the authority application states the reasons why this criterion cannot be satisfied; to enable confirmation of eligibility by the Medicare Australia CEO, current diagnostic reports of at least 1 of the following are required: (a) the level of serum M protein (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. magnetic resonance imaging or computed tomography scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration; as these parameters will be used to determine response, results of the above diagnostic reports must be provided with the authority application as follows: (i) for all patients, results for (a) or (b) or (c) must be provided;	

			(ii) where the patient has oligo-secretory or non-secretory multiple myeloma, (c) or (d) or if relevant (e), (f) or (g) must 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 (either previous or current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided	
	C3205		Where the patient is receiving treatment at/from a private or public hospital Continuing PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of multiple myeloma in a patient who has previously been issued with an authority prescription for lenalidomide and who does not have progressive disease, and where progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing, or the development of a new, soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause)	Compliance with modified Authority Required procedures
Lenograstim	C1005		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures
	C1046		Where the patient is receiving treatment at/from a private hospital Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C1051		Where the patient is receiving treatment at/from a private hospital Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.	Compliance with Written or Telephone Authority Required procedures
	C1097		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma	Compliance with Written or Telephone Authority Required procedures
	C1140		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures

	C1168		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures
	C1228		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy;	Compliance with Written or Telephone Authority Required procedures
	C1238		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures
	C1240		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)	Compliance with Written or Telephone Authority Required procedures
	C1249		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma	Compliance with Written or Telephone Authority Required procedures
	C1274		Where the patient is receiving treatment at/from a private hospital Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation;	Compliance with Written or Telephone Authority Required procedures
	C1324		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease	Compliance with Written or Telephone Authority Required procedures
	C1333		Where the patient is receiving treatment at/from a private hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma	Compliance with Written or Telephone Authority Required procedures
	C1555		Where the patient is receiving treatment at/from a private hospital Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors;	Compliance with Written or Telephone Authority Required procedures
	C3392		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3392
	C3393		Where the patient is receiving treatment at/from a public hospital Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code

				3393
	C3394		Where the patient is receiving treatment at/from a public hospital Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3394
	C3395		Where the patient is receiving treatment at/from a public hospital Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3395
	C3396		Where the patient is receiving treatment at/from a public hospital Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3396
	C3397		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3397
	C3398		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3398
	C3399		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3399

	C3400		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3400
	C3401		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3401
	C3402		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3402
	C3403		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3403
	C3404		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3404
	C3405		Where the patient is receiving treatment at/from a public hospital Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3405

Lopinavir with Ritonavir	C1832		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1833		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3315		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3315
	C3316		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with 2 or more other antiretroviral drugs, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3316
Maraviroc	C3286		Where the patient is receiving treatment at/from a private hospital In combination with other antiretrovirals, for the treatment of an antiretroviral experienced patient infected with only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) and: (a) evidence of HIV replication (viral load greater than 5,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. A patient must have virological failure of previous treatment with, or have resistance to, 3 different antiretroviral regimens, including regimens with: (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and (ii) at least 1 nucleoside reverse transcriptase inhibitor; and (iii) at least 2 protease inhibitors. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible	Compliance with Written or Telephone Authority Required procedures
	C3406		Where the patient is receiving treatment at/from a public hospital In combination with other antiretrovirals, for the treatment of an antiretroviral experienced patient infected with only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) and: (a) evidence of HIV replication (viral load greater than 5,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. A patient must have virological failure of previous treatment with, or have resistance to, 3 different antiretroviral regimens, including regimens with: (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and (ii) at least 1 nucleoside reverse transcriptase inhibitor; and (iii) at least 2 protease inhibitors. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3406

Methoxy polyethylene glycol-epoetin beta	C1957		Where the patient is receiving treatment at/from a private hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.	Compliance with Written or Telephone Authority Required procedures
	C3334		Where the patient is receiving treatment at/from a public hospital Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3334
Mycophenolic Acid	C1650		Where the patient is receiving treatment at/from a private hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C1651		Where the patient is receiving treatment at/from a private hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C3355		Where the patient is receiving treatment at/from a public hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3355
	C3356		Where the patient is receiving treatment at/from a public hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3356
Natalizumab	C3423		Where the patient is receiving treatment at/from a private hospital Initial treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, and where the diagnosis is confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan is included in the authority application, unless the authority application is accompanied by 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	Compliance with modified Authority Required procedures

	C3424		Where the patient is receiving treatment at/from a private hospital Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy.	Compliance with Written or Telephone Authority Required procedures
	C3425		Where the patient is receiving treatment at/from a public hospital Treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, and where: the diagnosis is confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan is included in the patient's medical notes, unless 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 is included in the patient's medical notes; natalizumab must be ceased if there is continuing progression of disability while on treatment with natalizumab; for continued treatment the patient must demonstrate compliance with, and an ability to tolerate, natalizumab	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3425
Nevirapine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Octreotide	C2622		Where the patient is receiving treatment at/from a private hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily	Compliance with Written or Telephone Authority Required procedures

	C2623		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour or VIPoma Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures
	C2624		Where the patient is receiving treatment at/from a private hospital Acromegaly Acromegaly in a patient controlled on Sandostatin subcutaneous injections. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months of treatment	Compliance with Written or Telephone Authority Required procedures
	C2625		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour or VIPoma Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections. 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 Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures
	C3407		Where the patient is receiving treatment at/from a public hospital Active acromegaly Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre and: (a) after failure of other therapy including dopamine agonists; or (b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or (c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3407
	C3408		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour or VIPoma Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3408

			be titrated slowly downwards to determine the minimum effective dose	
	C3409		Where the patient is receiving treatment at/from a public hospital Acromegaly Acromegaly in a patient controlled on Sandostatin subcutaneous injections. In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose). Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months of treatment	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3409
	C3410		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour or VIPoma Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) with symptom control on Sandostatin subcutaneous injections. 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 Sandostatin subcutaneous injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3410
Pamidronic Acid	C1035		Where the patient is receiving treatment at/from a private hospital Bone metastases from breast cancer.	Compliance with Written or Telephone Authority Required procedures
	C1233		Where the patient is receiving treatment at/from a private hospital Multiple myeloma;	Compliance with Written or Telephone Authority Required procedures
	C1500		Where the patient is receiving treatment at/from a private hospital Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.	Compliance with Written or Telephone Authority Required procedures
	C3341		Where the patient is receiving treatment at/from a public hospital Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3341
	C3342		Where the patient is receiving treatment at/from a public hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3342
	C3343		Where the patient is receiving treatment at/from a public hospital Bone metastases from breast cancer	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3343

Pegfilgrastim	C2912		Where the patient is receiving treatment at/from a private hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia;	Compliance with Written or Telephone Authority Required procedures
	C2917		Where the patient is receiving treatment at/from a private hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2918		Where the patient is receiving treatment at/from a private hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2919		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C2923		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures
	C2924		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures
	C2925		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures
	C2926		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures
	C2927		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures
	C2928		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures

	C2929		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures
	C2930		Where the patient is receiving treatment at/from a private hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures
	C3087		Where the patient is receiving treatment at/from a private hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned;	Compliance with Written or Telephone Authority Required procedures
	C3187		Where the patient is receiving treatment at/from a private hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.	Compliance with Written or Telephone Authority Required procedures
	C3357		Where the patient is receiving treatment at/from a public hospital For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3357
	C3362		Where the patient is receiving treatment at/from a public hospital A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3362
	C3363		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3363
	C3364		Where the patient is receiving treatment at/from a public hospital A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3364

			a good response to treatment is anticipated providing chemotherapy can be delivered as planned	
	C3365		Where the patient is receiving treatment at/from a public hospital A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3365
	C3369		Where the patient is receiving treatment at/from a public hospital A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3369
	C3370		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3370
	C3371		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3371
	C3372		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3372
	C3373		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3373

	C3374		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3374
	C3375		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3375
	C3376		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3376
	C3377		Where the patient is receiving treatment at/from a public hospital A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3377
Peginterferon Alfa-2a	C2334		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis C Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop	Compliance with Written or Telephone Authority Required procedures
	C2940		Where the patient is receiving treatment at/from a private hospital	Compliance with Written or Telephone Authority

			Chronic hepatitis B Monotherapy in patients with chronic hepatitis B and compensated liver disease who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B; (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception; (5) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L). Treatment is limited to 1 course of treatment for a duration of up to 48 weeks	Required procedures
	C3411		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Monotherapy in patients with chronic hepatitis B and compensated liver disease who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B; (4) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception; (5) Are not persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L). Treatment is limited to 1 course of treatment for a duration of up to 48 weeks	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3411
	C3412		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis C Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3412
Peginterferon Alfa-2b	C2334		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis C Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of	Compliance with Written or Telephone Authority Required procedures

			contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop	
	C3412		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis C Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. The treatment course is limited to up to 48 weeks. Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3412
Raltegravir	C3505		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C3506		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3507		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3507
	C3508		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3508
Ribavirin and Peginterferon Alfa-2a	C3053		Where the patient is receiving treatment at/from a private hospital Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria:	Compliance with Written or Telephone Authority Required procedures

			(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.	
	C3055		Where the patient is receiving treatment at/from a private hospital Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.	Compliance with Written or Telephone Authority Required procedures
	C3413		Where the patient is receiving treatment at/from a public hospital Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3413

			week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12	
	C3414		Where the patient is receiving treatment at/from a public hospital Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3414
Ribavirin and Peginterferon Alfa-2b	C3053		Where the patient is receiving treatment at/from a private hospital Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12.	Compliance with Written or Telephone Authority Required procedures
	C3055		Where the patient is receiving treatment at/from a private hospital Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks.	Compliance with Written or Telephone Authority Required procedures

			Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12.	
	C3413		Where the patient is receiving treatment at/from a public hospital Patients naive to interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. For patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 24 weeks. For hepatitis C patients with genotype 1, 4, 5 or 6 and those genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis, the treatment course is limited to 48 weeks. Patients with genotype 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop. (An HCV RNA assay at week 12 is unnecessary for genotype 2 and 3 patients because of the high likelihood of early viral response by week 12). Patients with genotype 1, 4, 5 or 6 who are viral positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after the first 24 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. Similarly, genotype 2 or 3 patients with hepatic cirrhosis or bridging fibrosis may only continue treatment after the first 24 weeks if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 24. An HCV RNA qualitative assay at week 24 is unnecessary for those patients with genotype 1, 4, 5 or 6 who became viral negative at week 12	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3413
	C3414		Where the patient is receiving treatment at/from a public hospital Patients who have failed one prior attempt at interferon based therapies (non-pegylated or pegylated) Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C and who satisfy all of the following criteria: (1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive); (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and both patient and their partner are using effective forms of contraception (one for each partner). Male patients and their partners are using effective forms of contraception (one for each partner). Female partners of male patients are not pregnant. The treatment course is limited to 48 weeks. Patients may only continue treatment after the first 12 weeks of treatment if plasma HCV RNA is not detectable by an HCV RNA qualitative assay at week 12	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3414

Rifabutin	C1299		Where the patient is receiving treatment at/from a private hospital Prophylaxis against *Mycobacterium avium* complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1435		Where the patient is receiving treatment at/from a private hospital Treatment of *Mycobacterium avium* complex infections in human immunodeficiency virus-positive patients	Compliance with Written or Telephone Authority Required procedures
	C3317		Where the patient is receiving treatment at/from a public hospital Prophylaxis against *Mycobacterium avium* complex infections in human immunodeficiency virus-positive patients with CD4 cell counts of less than 75 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3317
	C3415		Where the patient is receiving treatment at/from a public hospital Treatment of *Mycobacterium avium* complex infections in human immunodeficiency virus-positive patients	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3415
Ritonavir	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Rituximab	C3573		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 1 (patient recommencing after a break of more than 12 months)	Compliance with modified Authority Required procedures

			Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have severe active rheumatoid arthritis; and (b) have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF)-alfa antagonist; and (c) have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 12 months; and (d) have failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include: (i) 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: — hydroxychloroquine at a dose of at least 200 mg daily; or — leflunomide at a dose of at least 10 mg daily; or — sulfasalazine at a dose of at least 2 g daily; or (ii) if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose — at least 3 months continuous treatment with each of at least 2 of the following DMARDs: — hydroxychloroquine at a dose of at least 200 mg daily; and/or — leflunomide at a dose of at least 10 mg daily; and/or — sulfasalazine at a dose of at least 2 g daily; or (iii) 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 — at least 3 months continuous treatment with each of at least 2 DMARDs, one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: — azathioprine at a dose of at least 1 mg/kg per day; and/or — cyclosporin at a dose of at least 2 mg/kg/day; and/or — sodium aurothiomalate at a dose of 50 mg weekly; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, infliximab, golimumab, rituximab or tocilizumab; and where the following conditions apply: if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the authority application includes details of the contraindication or intolerance to methotrexate, and documents the maximum tolerated dose of methotrexate, if applicable; the authority application includes 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, the authority application provides details of the contraindication or intolerance and dose for each DMARD; failure to achieve an adequate response to the DMARD treatment specified above is demonstrated by the following: (a) 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 (b) either: (i) a total active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is 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 are determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy, and all measures are 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 authority application states the reason this criterion cannot be satisfied; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgement; a patient is eligible for treatment if they have not failed previous PBS-subsidised treatment with rituximab for rheumatoid arthritis, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; a course of initial treatment is limited to a maximum of 2 infusions	
	C3574		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — continuing treatment Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with rituximab; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment was with rituximab; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: an adequate response to treatment is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and 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 an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; a patient is eligible to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab, and the demonstration of response is submitted to the Medicare Australia CEO within 4 weeks of assessment; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment is limited to a maximum of 2 infusions; a patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, is eligible to receive a further course of rituximab under the continuing treatment	Compliance with modified Authority Required procedures

			restriction	
	C3582		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 2 (change or recommencement after a break of less than 12 months) Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have a documented history of severe active rheumatoid arthritis; and (b) have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF)-alfa antagonist; and (c) have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition within the previous 12 months and are eligible to receive further bDMARD therapy; and (d) have not failed previous PBS-subsidised treatment with rituximab for this condition; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: patients are eligible to receive further bDMARD therapy for rheumatoid arthritis provided they have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with rituximab and wishes to recommence therapy with this drug, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment; the response assessment included in the application is made at least 12 weeks after the first infusion of the course and is provided to the Medicare Australia CEO no later than 4 weeks from the date of assessment; a course of initial treatment is limited to a maximum of 2 infusions	Compliance with modified Authority Required procedures
Saquinavir	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310

Sevelamer	C3103		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures
	C3104		Where the patient is receiving treatment at/from a private hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures
	C3390		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3390
	C3391		Where the patient is receiving treatment at/from a public hospital Management (which includes initiation, stabilisation and review of therapy as required) of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3391
Sildenafil			**Definitions** For the purpose of PBS-subsidised supply of sildenafil for C 3172, C3173, C3174 and C3175: ***"PAH agent"*** means ambrisentan, bosentan, epoprostenol, iloprost, sildenafil or sitaxentan ***"Primary pulmonary hypertension and pulmonary arterial hypertension secondary to connective tissue disease"*** means: (i) pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or (iii) where right heart catheterisation cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function ***"Response to sildenafil or prior vasodilator treatment"*** means: (i) for adult patients with 2 or more baseline tests – as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (ii) for adult patients with an RHC composite assessment alone at baseline – as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iii) for adult patients with an ECHO composite assessment alone at baseline – as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital;	

			(iv) for patients aged less than 18 years – as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital	
	C3172		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 1 (new patients) Initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; and where the patient has failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) details of prior vasodilator treatment, including the dose and duration of treatment; and (4) where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information, details on the nature of the adverse event or contraindication; and (5) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone;	Compliance with modified Authority Required procedures

			determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3173		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 2 (new patients) Initial PBS-subsidised treatment with sildenafil citrate of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures
	C3174		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for all patients)	Compliance with modified Authority Required procedures

			Initial PBS-subsidised treatment with sildenafil citrate of patients: (a) who have World Health Organisation (WHO) Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, who wish to re-commence PBS-subsidised sildenafil citrate after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sildenafil citrate; or (b) who have WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sildenafil citrate; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3175		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment (all patients) Continuing PBS-subsidised treatment with sildenafil citrate of patients who have received approval for initial PBS-subsidised treatment with sildenafil citrate and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sildenafil citrate treatment; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that the test results included in the application are from the same tests as were conducted at baseline, except for patients who were able to undergo all 3 tests at baseline and whose subsequent ECHO composite assessment and 6MWT results demonstrate disease stability or improvement, in which case RHC composite assessment can be omitted: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or	Compliance with modified Authority Required procedures

			(iii) ECHO composite assessment plus 6MWT; or (iv) RHC composite assessment alone; or (v) ECHO composite assessment alone; and (2) where the same test or tests conducted at baseline cannot be performed on clinical grounds for assessment of response, a patient specific reason why the test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
Sirolimus	C1650		Where the patient is receiving treatment at/from a private hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C3355		Where the patient is receiving treatment at/from a public hospital Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3355
Sitaxentan			**Definitions** For the purpose of PBS-subsidised supply of sitaxentan for C 3176, C3177, C3178 and C3179: ***"PAH agent"*** means ambrisentan, bosentan, epoprostenol, iloprost, sildenafil or sitaxentan ***"Primary pulmonary hypertension and pulmonary arterial hypertension secondary to connective tissue disease"*** means: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or (ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or (iii) where right heart catheterisation cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function ***"Response to sitaxentan or prior vasodilator treatment"*** means: (i) for adult patients with 2 or more baseline tests – as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (ii) for adult patients with an RHC composite assessment alone at baseline – as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iii) for adult patients with an ECHO composite assessment alone at baseline – as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital; (iv) for patients aged less than 18 years – as at least one of the baseline tests demonstrating stability or improvement of	

			disease, as assessed by a physician from a designated hospital	
	C3176		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 1 (new patients) Initial PBS-subsidised treatment with sitaxentan sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; and where the patient has failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) details of prior vasodilator treatment, including the dose and duration of treatment; and (4) where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information, details on the nature of the adverse event or contraindication; and (5) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in	Compliance with modified Authority Required procedures

			the TGA-approved Product Information	
	C3177		Where the patient is receiving treatment at/from a private or public hospital Initial treatment 2 (new patients) Initial PBS-subsidised treatment with sitaxentan sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC), or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by echocardiography (ECHO); or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a RHC composite assessment plus ECHO composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that 1 of the test results submitted is a RHC composite assessment, unless RHC cannot be performed on clinical grounds: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (3) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures
	C3178		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (change or re-commencement for all patients) Initial PBS-subsidised treatment with sitaxentan sodium of patients:	Compliance with modified Authority Required procedures

			(a) who have World Health Organisation (WHO) Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, who wish to re-commence PBS-subsidised sitaxentan sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with sitaxentan sodium; or (b) who have WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than sitaxentan sodium; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes the test results based on which approval for the first application for PBS-subsidised PAH agent was granted; and (2) the date of the first application for PBS-subsidised treatment with a PAH agent; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and (4) where fewer than 3 tests (see requirement 1 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
	C3179		Where the patient is receiving treatment at/from a private or public hospital Continuing treatment (all patients) Continuing PBS-subsidised treatment with sitaxentan sodium of patients who have received approval for initial PBS-subsidised treatment with sitaxentan sodium and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of sitaxentan sodium treatment; and where the following conditions apply: the authority application is made in writing and includes: (1) a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT), or, where it is not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability, provided that the test results included in the application are from the same tests as were conducted at baseline, except for patients who were able to undergo all 3 tests at baseline and whose subsequent ECHO composite assessment and 6MWT results demonstrate disease stability or improvement, in which case RHC composite assessment can be omitted: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) ECHO composite assessment plus 6MWT; or	Compliance with modified Authority Required procedures

			(iv) RHC composite assessment alone; or (v) ECHO composite assessment alone; and (2) where the same test or tests conducted at baseline cannot be performed on clinical grounds for assessment of response, a patient specific reason why the test or tests could not be conducted; a maximum of 6 months of treatment will be authorised under this criterion; if less than 6 months of treatment is authorised for the written application under this criterion, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete 6 months of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	
Stavudine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Tacrolimus	C1654		Where the patient is receiving treatment at/from a private hospital Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures
	C3328		Where the patient is receiving treatment at/from a public hospital Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit, where management includes initiation, stabilisation and review of therapy as required	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3328

Telbivudine	C3052		Where the patient is receiving treatment at/from a private hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written or Telephone Authority Required procedures
	C3416		Where the patient is receiving treatment at/from a public hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3416
Tenofovir	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C2931		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) 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 (b) 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; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures

	C3203		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B Treatment, as sole PBS-subsidised therapy, of chronic hepatitis B in a patient who is nucleoside analogue naive and satisfies all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
	C3313		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) 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 (b) 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; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3313
	C3417		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Treatment, as sole PBS-subsidised therapy, of chronic hepatitis B in a patient who is nucleoside analogue naive and satisfies all of the following criteria:	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3417

			(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	
Tenofovir with Emtricitabine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Tenofovir with emtricitabine and efavirenz	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309

	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Thalidomide	C1233		Where the patient is receiving treatment at/from a private hospital Multiple myeloma.	Compliance with Written or Telephone Authority Required procedures
	C3342		Where the patient is receiving treatment at/from a public hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3342
Tipranavir	C2700		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of human immunodeficiency virus (HIV) infection in antiretroviral experienced adults with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included: (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and (ii) at least 1 nucleoside reverse transcriptase inhibitor; and (iii) at least 2 protease inhibitors	Compliance with Written or Telephone Authority Required procedures
	C3418		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of human immunodeficiency virus (HIV) infection in antiretroviral experienced adults with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included: (i) at least 1 non-nucleoside reverse transcriptase inhibitor; and (ii) at least 1 nucleoside reverse transcriptase inhibitor; and (iii) at least 2 protease inhibitors	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3418
	C3500		Where the patient is receiving treatment at/from a private hospital Treatment, in combination with other antiretroviral agents, and co-administered with ritonavir, of human immunodeficiency virus (HIV) infection in an antiretroviral experienced patient with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens, including	Compliance with Written or Telephone Authority Required procedures

			regimens with at least (i) 1 non-nucleoside reverse transcriptase inhibitor, (ii) 1 nucleoside reverse transcriptase inhibitor, and (iii) at least 2 protease inhibitors	
	C3501		Where the patient is receiving treatment at/from a public hospital Treatment, in combination with other antiretroviral agents, and co-administered with ritonavir, of human immunodeficiency virus (HIV) infection in an antiretroviral experienced patient with: (a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or (b) CD4 cell counts of less than 500 per cubic millimetre. Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens, including regimens with at least (i) 1 non-nucleoside reverse transcriptase inhibitor, (ii) 1 nucleoside reverse transcriptase inhibitor, and (iii) at least 2 protease inhibitors	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3501
Tocilizumab	C3480		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 3 Initial PBS-subsidised supply for continuing treatment with tocilizumab, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who: (a) has a documented history of severe active rheumatoid arthritis; and (b) was receiving treatment with tocilizumab prior to 1 July 2009; and (c) has demonstrated a response to tocilizumab treatment, as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and (d) is receiving treatment with tocilizumab at the time of application; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgement; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; a patient is eligible for PBS-subsidised treatment under the above criteria once only	Compliance with modified Authority Required procedures
	C3559		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 1 (new patient or patient recommencing after a break of more than 12 months) Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have severe active rheumatoid arthritis; and (b) have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 12 months; and (c) have failed to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include: (i) 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: — hydroxychloroquine at a dose of at least 200 mg daily; or — leflunomide at a dose of at least 10 mg daily; or	Compliance with modified Authority Required procedures

			— sulfasalazine at a dose of at least 2 g daily; or (ii) if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose — at least 3 months continuous treatment with each of at least 2 of the following DMARDs: — hydroxychloroquine at a dose of at least 200 mg daily; and/or — leflunomide at a dose of at least 10 mg daily; and/or — sulfasalazine at a dose of at least 2 g daily; or (iii) 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 — at least 3 months continuous treatment with each of at least 2 DMARDs, one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: — azathioprine at a dose of at least 1 mg/kg per day; and/or — cyclosporin at a dose of at least 2 mg/kg/day; and/or — sodium aurothiomalate at a dose of 50 mg weekly; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, infliximab, golimumab, rituximab or tocilizumab; and where the following conditions apply: if methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the authority application includes details of the contraindication or intolerance to methotrexate, and documents the maximum tolerated dose of methotrexate, if applicable; the authority application includes 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, the authority application provides details of the contraindication or intolerance and dose for each DMARD; failure to achieve an adequate response to the DMARD treatment specified above is demonstrated by the following: (a) 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 (b) either: (i) a total active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is 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 are determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy, and all measures are 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 authority application states the reason this criterion cannot be satisfied; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgement; a patient is eligible for treatment if they have not failed previous PBS-subsidised treatment with tocilizumab for rheumatoid arthritis, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; a course of initial treatment is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for	

			supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	
	C3560		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — initial treatment 2 (change or recommencement after a break of less than 12 months) Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who: (a) have a documented history of severe active rheumatoid arthritis; and (b) have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition within the previous 12 months and are eligible to receive further bDMARD therapy; and (c) have not failed previous PBS-subsidised treatment with tocilizumab for this condition; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: patients are eligible to receive further bDMARD therapy for rheumatoid arthritis provided they have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times; patients who demonstrate a response to a course of PBS-subsidised treatment with rituximab and who wish to transfer to treatment with tocilizumab are not eligible to commence treatment with tocilizumab until they have completed a period free from PBS-subsidised bDMARD treatment of at least 22 weeks duration, immediately following the second rituximab infusion; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with tocilizumab and wishes to recommence therapy with this drug, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised tocilizumab treatment is a 16-week initial treatment course, is made following a minimum of 12 weeks of therapy; a course of initial treatment is limited to a maximum of 16 weeks of treatment; if less than 16 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 16 weeks of treatment in total may be submitted by telephone	Compliance with modified Authority Required procedures
	C3561		Where the patient is receiving treatment at/from a private or public hospital Rheumatoid arthritis — continuing treatment Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or by a clinical immunologist with expertise in the management of rheumatoid arthritis, of adults: (a) who have a documented history of severe active rheumatoid arthritis; and (b) who have demonstrated an adequate response to treatment with tocilizumab; and (c) whose most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment was with tocilizumab; and where bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab; and where the following conditions apply: an adequate response to treatment is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and	Compliance with modified Authority Required procedures

			(b) either of the following: (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 joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and 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 an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Rheumatoid Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with tocilizumab; the response assessment included in the application is provided to the Medicare Australia CEO no later than 4 weeks from the cessation of the treatment course; if the most recent course of tocilizumab therapy is a 16-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone	
Valaciclovir	C1494		Where the patient is receiving treatment at/from a private hospital Prophylaxis of cytomegalovirus infection and disease following renal transplantation in patients at risk of cytomegalovirus disease	Compliance with Written or Telephone Authority Required procedures
	C3419		Where the patient is receiving treatment at/from a public hospital Prophylaxis of cytomegalovirus infection and disease following renal transplantation in patients at risk of cytomegalovirus disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3419
Valganciclovir	C1620		Where the patient is receiving treatment at/from a private hospital Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome;	Compliance with Written or Telephone Authority Required procedures
	C1964		Where the patient is receiving treatment at/from a private hospital Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease.	Compliance with Written or Telephone Authority Required procedures
	C3420		Where the patient is receiving treatment at/from a public hospital Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code

				3420
	C3421		Where the patient is receiving treatment at/from a public hospital Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3421
Zidovudine	C1820		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures
	C1821		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures
	C3309		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with CD4 cell counts of less than 500 per cubic millimetre	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3309
	C3310		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus infection in patients with viral load of greater than 10,000 copies per mL	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3310
Zoledronic Acid	C1035		Where the patient is receiving treatment at/from a private hospital Bone metastases from breast cancer;	Compliance with Written or Telephone Authority Required procedures
	C1233		Where the patient is receiving treatment at/from a private hospital Multiple myeloma;	Compliance with Written or Telephone Authority Required procedures
	C1500		Where the patient is receiving treatment at/from a private hospital Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.	Compliance with Written or Telephone Authority Required procedures
	C1797		Where the patient is receiving treatment at/from a private hospital Bone metastases from hormone-resistant prostate cancer, with demonstration of biochemical progression of disease despite	Compliance with Written or Telephone Authority

			maximal therapy with hormonal treatments;	Required procedures
	C3341		Where the patient is receiving treatment at/from a public hospital Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3341
	C3342		Where the patient is receiving treatment at/from a public hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3342
	C3343		Where the patient is receiving treatment at/from a public hospital Bone metastases from breast cancer	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3343
	C3422		Where the patient is receiving treatment at/from a public hospital Bone metastases from hormone-resistant prostate cancer, with demonstration of biochemical progression of disease despite maximal therapy with hormonal treatments	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3422

Schedule 4 Patient contributions

Listed drug	Form (strength, type, size, etc.)	Manner of administration	Brand	Quantity or Number of Units	Approved ex-manufacturer price $	Claimed ex-manufacturer price $
Cyclosporin	Capsule 25 mg	Oral	Neoral 25	30	39.98	40.93
	Capsule 50 mg	Oral	Neoral 50	30	83.17	84.20
	Capsule 100 mg	Oral	Neoral 100	30	169.46	170.50
Desferrioxamine	Powder for injection containing desferrioxamine mesylate 500 mg	Injection	Desferal 500 mg	10	95.08	102.95
	Powder for injection containing desferrioxamine mesylate 2 g	Injection	Desferal 2 g	1	38.03	38.42

Note

1. All legislative instruments and compilations are registered on the Federal Register of legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au.