PB 79 of 2011

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011[1]

National Health Act 1953

I, FELICITY McNEILL, Acting First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing, delegate of the Minister for Health and Ageing, make this Special Arrangement under subsection 100 (1) of the *National Health Act 1953*.

Dated 23 November 2011

FELICITY McNEILL
Acting First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing

Page

Contents

Part 1 General

Division 1 Preliminary

1 Name of Special Arrangement

(1) This Special Arrangement is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*.

(2) This Special Arrangement may also be cited as PB 79 of 2011.

2 Commencement

This Special Arrangement commences on 1 December 2011.

3 Definitions

In this Special Arrangement:

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

Act means the *National Health Act 1953*.

authorised prescriber means:

(a) for a chemotherapy pharmaceutical benefit — a kind of person identified by a prescriber code mentioned in the column in Part 1 of Schedule 1 headed 'Authorised Prescriber' for the benefit; or

(b) for a related pharmaceutical benefit — a kind of person identified by a prescriber code mentioned in the column in Schedule 2 headed 'Authorised Prescriber' for the benefit.

authority prescription means a prescription or medication chart (including an infusion prescription or infusion medication chart) that has been authorised:

(a) in accordance with regulation 13 of the Regulations as modified by this Special Arrangement; or

(b) in accordance with Division 3 of Part 2 of this Special Arrangement.

benefit card means any of the following:

(a) a PBS Entitlement Card;

(b) a PBS Safety Net Concession Card;

(c) a Pensioner Concession Card;

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

(e) a Commonwealth Seniors Health Card;

(f) a cleft lip and cleft palate identification card;

(g) a DVA Gold Card;

(h) a DVA White Card;

(i) a DVA Orange Card;

(j) War Widow/Widower Transport Card;

(k) a card or voucher approved by the Chief Executive Medicare for this paragraph.

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

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

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

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

diluent fee means an amount of $4.75.

dispensing fee means an amount of $6.42.

distribution fee means an amount of $24.

dose, for a chemotherapy drug, means the quantity of the drug contained in an infusion.

eligible patient means a person who:

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

(b) is receiving treatment from an authorised prescriber.

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

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

HSD hospital authority means a public hospital authority approved by the Chief Executive Medicare under section 52 of the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010*.

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

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

infusion medication chart means a medication chart directing the supply of an infusion.

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

non-approved public hospital authority means a public hospital authority that is not an approved hospital authority or an HSD hospital authority.

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

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

preparation fee means an amount of $40.

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

(a) MP — medical practitioner;

(b) PDP — participating dental practitioner;

(c) AO — authorised optometrist;

(d) MW — authorised midwife;

(e) NP — authorised nurse practitioner.

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

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

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

Streamlined Authority Code means the number mentioned in subsection 22 (5).

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

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

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

Division 2 Pharmaceutical benefits

4 Pharmaceutical benefits covered by this Special Arrangement

(1) This Special Arrangement applies to each pharmaceutical benefit mentioned in Part 1 of Schedule 1 or in Schedule 2.

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

(a) in the form mentioned in Part 1 of Schedule 1 or in Schedule 2 for the listed drug; and

(b) with the manner of administration mentioned in Part 1 of Schedule 1 or in Schedule 2 for the form of the listed drug.

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

5 Application of Part VII of the Act

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

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

(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.

6 Responsible person

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

(2) For subsection (1):

(a) the person is the person mentioned in Schedule 3 for the code, with the ABN, if any, mentioned in Schedule 3 for the person; and

(b) the pharmaceutical item is the listed drug mentioned in Part 1 of Schedule 1 or in Schedule 2:

(i) in the form mentioned in Part 1 of Schedule 1 or in Schedule 2 for the listed drug; and

(ii) with the manner of administration mentioned in Part 1 of Schedule 1 or in Schedule 2 for the form of the listed drug.

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

7 Authorised prescriber

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

Federal Register of Legislative Instruments F2011L02491

(2) Only an authorised prescriber for a related pharmaceutical benefit may prescribe the supply of the related pharmaceutical benefit to an eligible patient.

Note Each person mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Authorised Prescriber' is authorised by subsection 88 (1) of the Act, or has been authorised by the Minister under section 88 of the Act, to prescribe the pharmaceutical benefit.

8 Prescription circumstances

(1) If at least one circumstances code is mentioned in the column in Part 1 of Schedule 1 headed 'Circumstances' for a chemotherapy pharmaceutical benefit, the circumstances in Schedule 4 for a code are circumstances in which the supply of an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit may be prescribed.

(2) If each chemotherapy pharmaceutical benefit that has the same chemotherapy drug has at least one circumstances code, then the supply of an infusion that includes the chemotherapy drug may only be prescribed in circumstances mentioned for a circumstances code.

(3) If at least one circumstances code is mentioned in the column in Schedule 2 headed 'Circumstances' for a related pharmaceutical benefit:

(a) the circumstances mentioned in Schedule 4 for a code are circumstances in which the related pharmaceutical benefit may be prescribed; and

(b) the related pharmaceutical benefit may only be prescribed in circumstances mentioned for a circumstances code.

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

9 Maximum amount – chemotherapy drug

(1) This section applies subject to section 17.

(2) The maximum amount of a chemotherapy drug that an authorised prescriber may direct to be included in an infusion in one infusion prescription or infusion medication chart is the amount mentioned in the column in Part 2 of Schedule 1 headed 'Maximum Amount' for the chemotherapy drug.

(3) If at least one purposes code is mentioned in the column in Part 2 of Schedule 1 headed 'Purposes' for a chemotherapy drug, the amount mentioned in the column headed 'Maximum Amount' is the maximum for the particular purposes mentioned in Schedule 4 for each code.

Federal Register of Legislative Instruments F2011L02491

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

10 Maximum quantity – related pharmaceutical benefit

(1) This section applies subject to section 21.

(2) The maximum quantity or number of units of the pharmaceutical item in a related pharmaceutical benefit that an authorised prescriber may direct to be supplied in one prescription or medication chart is the quantity or number of units mentioned in the column in Schedule 2 headed 'Maximum Quantity' for the pharmaceutical benefit.

(3) If at least one purposes code is mentioned in the column in Schedule 2 headed 'Purposes' for a related pharmaceutical benefit, the quantity or number of units mentioned in the column headed 'Maximum Quantity' is the maximum for the particular purposes mentioned in Schedule 4 for each code.

(4) If no purposes code is mentioned in the column in Schedule 2 headed 'Purposes', the quantity or number of units mentioned in the column headed 'Maximum Quantity' is the maximum for all purposes, other than a purpose for which a different maximum is mentioned for the same related pharmaceutical benefit.

(5) For subsection (2), the pharmaceutical item is the listed drug mentioned in Schedule 2:

(a) in the form mentioned in Schedule 2 for the listed drug; and

(b) with the manner of administration mentioned in Schedule 2 for the form of the listed drug.

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

11 Maximum number of repeats – chemotherapy drug

(1) This section applies subject to section 17.

(2) The maximum number of occasions an authorised prescriber may, in one infusion prescription or infusion medication chart, direct that the supply of an infusion containing a chemotherapy drug be repeated is the number in the column in Part 2 of Schedule 1 headed 'Number of Repeats' for the chemotherapy drug.

(3) If at least one purposes code is mentioned in the column in Part 2 of Schedule 1 headed 'Purposes' for the chemotherapy drug, the number of repeats mentioned in the column headed 'Number of Repeats' is the maximum number for the particular purposes mentioned in Schedule 4 for each code.

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

(5) If an infusion contains more than one chemotherapy drug, the maximum number of repeats for the infusion is the smallest maximum number that applies in relation to one of the chemotherapy drugs.

12 Maximum number of repeats – related pharmaceutical benefit

(1) This section applies subject to section 21.

(2) The maximum number of occasions an authorised prescriber may, in one prescription or medication chart, direct that the supply of a related pharmaceutical benefit be repeated is the number in the column in Schedule 2 headed 'Number of Repeats' for the related pharmaceutical benefit.

(3) If at least one purposes code is mentioned in the column in Schedule 2 headed 'Purposes' for the related pharmaceutical benefit, the number of repeats mentioned in the column headed 'Number of Repeats' is the maximum number for the particular purposes mentioned in Schedule 4 for each code.

(4) If no purposes code is mentioned in the column in Schedule 2 headed 'Purposes', the number of repeats mentioned in the column headed 'Number of Repeats' is the maximum number for all purposes, other than a purpose for which a different maximum is mentioned for the same related pharmaceutical benefit.

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

13 Section 100 only supply

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

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

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

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

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

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

(5) If the letter 'C' is mentioned in the column in Part 1 of Schedule 1 or in Schedule 2 headed 'Section 100 only' for a pharmaceutical benefit and a code is mentioned in the column headed 'Circumstances', the pharmaceutical benefit may be supplied in the circumstances signified by the code only in accordance with this Special Arrangement and any other Special Arrangement relating to the pharmaceutical benefit.

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

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

Part 2 Prescription

Division 1 Chemotherapy pharmaceutical benefits

14 Methods of prescribing chemotherapy pharmaceutical benefit

(1) An authorised prescriber may prescribe a chemotherapy pharmaceutical benefit under this Special Arrangement by:

(a) writing an infusion prescription for an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit, in accordance with regulation 19 of the Regulations as modified by section 15; or

(b) for an eligible public hospital patient — preparing an infusion medication chart for an infusion that includes the chemotherapy drug in the chemotherapy pharmaceutical benefit, in accordance with section 16.

(2) However, chemotherapy pharmaceutical benefits containing the following chemotherapy drugs may only be prescribed by writing an infusion prescription:

(a) bortezomib;

(b) trastuzumab.

(3) An infusion prescription written in accordance with section 15 or an infusion medication chart prepared in accordance with section 16 is taken to be a duly written prescription for regulation 19 of the Regulations.

(4) Paragraph 19 (2) (a) of the Regulations does not apply to an infusion prescription or infusion medication chart.

15 Information to be included in infusion prescription

(1) For paragraph 14 (1) (a), this section modifies the requirements of regulation 19 of the Regulations.

(2) An infusion prescription must include the following information:

(a) the name of each chemotherapy drug included in the infusion;

(b) the dose of each chemotherapy drug;

(c) if supply of the infusion is to be repeated — the number of times it is to be repeated;

(d) for an authority prescription, in relation to each circumstance for which authorisation of the prescription is required:

(i) the authority approval number allotted to the prescription by the Chief Executive Medicare, unless the prescription is to be posted or delivered to the Chief Executive Medicare for authorisation; or

Federal Register of Legislative Instruments F2011L02491

(ii) the Streamlined Authority Code.

(3) An infusion prescription does not need to include the following information:

(a) the form of a chemotherapy drug to be supplied;

(b) the quantity or number of units of a pharmaceutical benefit to be supplied;

(c) the number of times supply of a pharmaceutical benefit is to be repeated.

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

16 Information to be included in infusion medication chart

For paragraph 14 (1) (b), an infusion medication chart for an eligible public hospital 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 authorised prescriber;

(c) the Streamlined Authority Code for each circumstance, if any, in relation to which authorisation of the medication chart is required;

(d) the patient's name and address;

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

(f) the letters 'PBS' or 'RPBS', whichever is applicable;

(g) the name of each chemotherapy drug included in the infusion;

(h) the dose of each chemotherapy drug;

(i) the number of repeats of the infusion;

(j) the date the medication chart is prepared.

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

17 Dose or number of repeats greater than maximum

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

(a) for an infusion prescription written in accordance with paragraph 14 (1) (a) — the prescription must be authorised in accordance with the procedures mentioned in regulation 13 of the Regulations as modified by subsection (2); and

(b) for an infusion medication chart prepared in accordance with paragraph 14 (1) (b) — the medication chart must be authorised in accordance with the procedures mentioned in section 28.

Federal Register of Legislative Instruments F2011L02491

(2) A reference in regulation 13 of the Regulations to a determination in force under paragraph 85A (2) (a) of the Act is to be read as a reference to the maximum amount of the chemotherapy drug as described in section 9.

(3) If an authorised prescriber directs that the supply of an infusion be repeated more times than the maximum number of repeats permitted under section 11 for one or more of the chemotherapy drugs included in the infusion, then:

(a) for an infusion prescription written in accordance with paragraph 14 (1) (a) — the prescription must be authorised in accordance with the procedures mentioned in regulation 13 of the Regulations as modified by subsection (4); and

(b) for an infusion medication chart prepared in accordance with paragraph 14 (1) (b) — the medication chart must be authorised in accordance with the procedures mentioned in section 28.

(4) A reference in regulation 13 of the Regulations to a determination in force under paragraph 85A (2) (b) of the Act is to be read as a reference to the maximum number of repeats for a chemotherapy drug as described in section 11.

18 Direction to vary dose of chemotherapy drug in infusion

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

(2) A new dose directed under subsection (1) that is greater than the maximum amount for the chemotherapy drug does not require approval under section 17.

(3) If a supplier receives a direction in accordance with subsection (1), the supplier must record on the infusion prescription or infusion medication chart:

(a) the name of the authorised prescriber who gave the direction; and

(b) the means by which the supplier was notified of the direction (for example, by phone or by fax); and

(c) the date and time the supplier was notified.

Division 2 Related pharmaceutical benefits

19 Methods of prescribing related pharmaceutical benefit

(1) An authorised prescriber may prescribe a related pharmaceutical benefit under this Special Arrangement by:

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

(b) preparing a medication chart for the related pharmaceutical benefit in accordance with section 20.

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

(2) A medication chart prepared in accordance with section 20 is taken to be a duly written prescription for regulation 19 of the Regulations.

20 Information to be included in medication chart for related pharmaceutical benefit

For paragraph 19 (1) (b), a medication chart for an eligible public hospital patient in relation to a related pharmaceutical benefit 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 authorised prescriber;

(c) if the circumstance in which the related pharmaceutical benefit is being prescribed requires authorisation — the Streamlined Authority Code;

(d) the patient's name and address;

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

(f) the letters 'PBS' or 'RPBS', whichever is applicable;

(g) the listed drug in the related pharmaceutical benefit;

(h) the strength of the related pharmaceutical benefit;

(i) the quantity or dosage, or both, of the related pharmaceutical benefit;

(j) if the dosage is provided — how often the dosage is to be taken by the patient and the period that the pharmaceutical benefit is prescribed;

(k) the number of repeats;

(l) the date the medication chart is prepared.

21 Quantity or number of repeats greater than maximum

(1) If an authorised prescriber prescribes a supply of a related pharmaceutical benefit that is greater than the maximum quantity or number of units permitted under section 10, then:

(a) for a prescription written in accordance with paragraph 19 (1) (a) — the prescription must be authorised in accordance with the procedures mentioned in regulation 13 of the Regulations; and

(b) for a medication chart prepared in accordance with paragraph 19 (1) (b) — the medication chart must be authorised in accordance with the procedures mentioned in section 28.

Federal Register of Legislative Instruments F2011L02491

(2) If an authorised prescriber directs that the supply of a related pharmaceutical benefit be repeated more times than the maximum number of repeats permitted under section 12, then:

(a) for a prescription written in accordance with paragraph 19 (1) (a) — the prescription must be authorised in accordance with the procedures mentioned in regulation 13 of the Regulations; and

(b) for a medication chart prepared in accordance with paragraph 19 (1) (b) — the medication chart must be authorised in accordance with the procedures mentioned in section 28.

Division 3 Authority required procedures

22 Authority required procedures to be followed

(1) This section applies to an infusion prescription or infusion medication chart if:

(a) a circumstances code is mentioned in Part 1 of Schedule 1 for a chemotherapy pharmaceutical benefit that has a chemotherapy drug included in the infusion; and

(b) the supply of the infusion is prescribed in the circumstances mentioned in Schedule 4 for the code; and

(c) the circumstances include one of the following statements:

(i) Compliance with Authority Required procedures;

(ii) Compliance with Written Authority Required procedures;

(iii) Compliance with Telephone Authority Required procedures;

(iv) Compliance with Written or Telephone Authority Required procedures;

(v) Compliance with modified Written Authority Required procedures.

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

(2) This section applies to a prescription or medication chart for a related pharmaceutical benefit if:

(a) a circumstances code is mentioned in Schedule 2 for the related pharmaceutical benefit; and

(b) the related pharmaceutical benefit is prescribed in the circumstances mentioned in Schedule 4 for the code; and

(c) the circumstances include one of the following statements:

(i) Compliance with Authority Required procedures;

(ii) Compliance with Written Authority Required procedures;

(iii) Compliance with Telephone Authority Required procedures;

(iv) Compliance with Written or Telephone Authority Required procedures;

(v) Compliance with modified Written Authority Required procedures.

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

(3) The table sets out which procedure in this Division must be followed for:

(a) an infusion prescription written in accordance with paragraph 14 (1) (a) to be authorised in the circumstances mentioned in Schedule 4; or

(b) a prescription written in accordance with paragraph 19 (1) (a) to be authorised in the circumstances mentioned in Schedule 4.

If the circumstances in Schedule 4 include the statement …	**the procedure that must be followed is …**
Compliance with Authority Required procedures	any one of the Written Authority Required procedure set out in section 23, the Telephone Authority Required procedure set out in section 26 or the Electronic Authority Required procedure set out in section 27
Compliance with Written Authority Required procedures	the Written Authority Required procedure set out in section 23
Compliance with Telephone Authority Required procedures	the Telephone Authority Required procedure set out in section 26
Compliance with Written or Telephone Authority Required procedures	either the Written Authority Required procedure set out in section 23 or the Telephone Authority Required procedure set out in section 26
Compliance with modified Written Authority Required procedures	the modified Written Authority Required procedure set out in section 24

(4) The procedure set out in section 28 must be followed for:

(a) an infusion medication chart prepared in accordance with paragraph 14 (1) (b) to be authorised in the circumstances mentioned in Schedule 4; or

(b) a medication chart prepared in accordance with paragraph 19 (1) (b) to be authorised in the circumstances mentioned in Schedule 4.

(5) However, if the circumstances mentioned in Schedule 4 include the words 'Streamlined Authority Code' followed by a number:

(a) a prescription written in accordance with paragraph 14 (1) (a) is taken to be authorised if the authorised prescriber has:

(i) prepared and signed the prescription in accordance with paragraph 23 (1) (a), (b), (c) or (d); and

Federal Register of Legislative Instruments F2011L02491

(ii) has written the Streamlined Authority Code for the circumstances on the prescription; and

(b) a prescription written in accordance with paragraph 19 (1) (a) is taken to be authorised if the authorised prescriber has:

(i) prepared and signed the prescription in accordance with paragraph 23 (1) (a), (b), (c) or (d); and

(ii) has written the Streamlined Authority Code for the circumstances on the prescription; and

(c) a medication chart prepared in accordance with paragraph 14 (1) (b) or 19 (1) (b) is taken to be authorised.

23 Written Authority Required procedure

(1) To have a prescription authorised using the Written Authority Required procedure, the authorised prescriber must deliver or post to the Chief Executive Medicare the prescription prepared and signed by the authorised prescriber:

(a) in a form approved by the Secretary and completed by the authorised prescriber in ink in his or her own handwriting; or

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

(c) 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

(d) by a method approved in writing by the Secretary.

(2) A prescription submitted in accordance with subsection (1) may be authorised by the Chief Executive Medicare signing his or her authorisation on the prescription, and:

(a) if the Chief Executive Medicare requires the authorised prescriber to alter the prescription — returning it to the authorised prescriber for alteration before the authorised prescriber gives it to the person in respect of whom it was prepared; or

(b) in any other case, either:

(i) returning the authorised prescription to the authorised prescriber; or

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

24 Modified Written Authority Required procedure

(1) To have a prescription authorised using the modified Written Authority Required procedure, the authorised prescriber:

(a) must submit the prescription in accordance with subsection 23 (1); and

(b) must comply with any other requirements included in the circumstances in Schedule 4 that apply to the prescription.

Example

The circumstances in Schedule 4 require additional documents to be submitted along with the prescription.

(2) A prescription submitted in accordance with subsection (1) may be authorised by the Chief Executive Medicare in the way set out in subsection 23 (2).

25 Submission of prescription by agent permitted

For sections 23 and 24, a prescription prepared and signed by an authorised prescriber is taken to have been submitted by the authorised prescriber if it is submitted by his or her agent.

26 Telephone Authority Required procedure

(1) To have a prescription authorised using the Telephone Authority Required procedure, the authorised prescriber must submit to the Chief Executive Medicare, by telephone, details of the prescription prepared and signed by the authorised prescriber in accordance with paragraph 23 (1) (a), (b), (c) or (d).

(2) However, if the authorised prescriber is unable to submit the prescription because the telephone system established by the Chief Executive Medicare for that purpose is unavailable, the authorised prescriber must submit the prescription in accordance with the instructions in an emergency telephone message provided by the Chief Executive Medicare.

(3) A prescription submitted in accordance with subsection (1) may be authorised by the Chief Executive Medicare telling the authorised prescriber by telephone, at the time the Chief Executive Medicare is given the details of the prescription, that the prescription is authorised.

(4) If the Chief Executive Medicare authorises a prescription under subsection (3):

(a) the Chief Executive Medicare must tell the authorised prescriber by telephone the number given by the Chief Executive Medicare to the prescription; and

(b) the authorised prescriber 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.

(5) A prescription submitted in accordance with subsection (2) is taken to have been authorised by the Chief Executive Medicare if the authorised prescriber completes the prescription in accordance with the instructions given in the emergency telephone message.

27 Electronic Authority Required procedure

(1) To have a prescription authorised using the Electronic Authority Required procedure, the authorised prescriber must submit to the Chief Executive Medicare, by means of an electronic communication of a kind approved in writing by the Chief Executive Medicare, details of the prescription prepared and signed by the authorised prescriber in accordance with paragraph 23 (1) (a), (b), (c) or (d).

(2) A prescription submitted in accordance with subsection (1) may be authorised by the Chief Executive Medicare sending his or her authorisation by electronic communication to the authorised prescriber.

(3) If the Chief Executive Medicare authorises a prescription under subsection (2):

(a) the Chief Executive Medicare must tell the authorised prescriber by electronic communication the number given by the Chief Executive Medicare to the prescription; and

(b) the authorised prescriber 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.

28 Medication chart authorisation

(1) To have a medication chart authorised, a pharmacist employed or engaged by the public hospital authority must, on behalf of the authorised prescriber, submit the information in the chart mentioned in section 16 or 20 to the Chief Executive Medicare by means of an electronic communication of a kind approved by the Chief Executive Medicare.

(2) A medication chart for which information has been submitted in accordance with subsection (1) is taken to have been authorised when:

(a) the pharmacist receives a message by electronic communication from the system established by the Chief Executive Medicare indicating that the authorisation has been granted; and

(b) the pharmacist completes the medication chart in accordance with the instructions given by the message.

29 Alternative if medication chart not authorised

(1) This section applies if:

(a) a pharmacist attempted to comply with subsection 28 (1) but was unable to do so because the system established by the Chief Executive Medicare for the provision of authorisations was unavailable; or

(b) a pharmacist submitted information for a medication chart in accordance with subsection 28 (1) but the authorisation was not granted by the system established by the Chief Executive Medicare.

(2) An authorisation for the supply of the infusion in the circumstances requiring authorisation may be obtained if the authorised prescriber prepares an infusion prescription in accordance with paragraph 14 (1) (a) and submits the infusion prescription in accordance with a procedure allowed by subsection 22 (3) for the prescription.

(3) An authorisation for the supply of the related pharmaceutical benefit in the circumstances requiring authorisation may be obtained if the authorised prescriber prepares a prescription in accordance with paragraph 19 (1) (a) and submits the prescription in accordance with a procedure allowed by subsection 22 (3) for the prescription.

Part 3 Supply

30 Entitlement to infusion or related pharmaceutical benefit

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

31 Supply of infusion under this Special Arrangement

(1) An infusion may be supplied under this Special Arrangement by any of the following:

(a) an approved pharmacist;

(b) an approved medical practitioner;

(c) an approved hospital authority for a private hospital;

(d) a public hospital authority to an eligible public hospital patient.

(2) However, a public hospital authority that is not a participating hospital authority may only supply an infusion that contains trastuzumab and that does not contain any other chemotherapy drug.

(3) An infusion that is prescribed in an infusion medication chart may only be supplied by a participating hospital authority to an eligible public hospital patient.

32 Supply of related pharmaceutical benefits under this Special Arrangement

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

33 Selection of chemotherapy pharmaceutical benefits to make infusion

Form, brand and method of administering

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

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

(3) If an authorised prescriber identifies a method of administering a chemotherapy drug in an infusion prescription or infusion medication chart, the supply of the infusion must be consistent with the method.

(4) Subsection (3) applies regardless of whether the method identified by the authorised prescriber is also a manner of administration for one or more chemotherapy pharmaceutical benefits containing the chemotherapy drug.

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

Quantity and number of repeats

(5) If an authorised prescriber directs the supply of a quantity or number of units of a particular chemotherapy pharmaceutical benefit, the supplier of the infusion may disregard the direction.

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

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

Circumstances

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

Note If this subsection applies, an authority approval number or Streamlined Authority Code will appear on the infusion prescription or infusion medication chart — see sections 15 and 16 and Division 3 of Part 2.

34 Modified application of Act and Regulations

Infusions

(1) A supply of an infusion under this Special Arrangement is not an early supply of a specified pharmaceutical benefit within the meaning of subsection 84AAA (1) of the Act.

(2) Subregulations 25 (2) to (4) of the Regulations do not apply to the supply of an infusion under this Special Arrangement.

Note The effect of those subregulations is to restrict how soon a repeat supply may be made. There is no restriction on how soon a repeat supply of an infusion may be made under this Special Arrangement.

(3) Regulations 24 and 26A of the Regulations do not apply to the supply of an infusion under this Special Arrangement.

(4) A reference elsewhere in the Regulations to the supply of a pharmaceutical benefit is taken to include the supply of an infusion under this Special Arrangement.

Medication charts

(5) Regulations 22 and 31 of the Regulations do not apply to:

(a) the supply of an infusion that is prescribed in an infusion medication chart in accordance with paragraph 14 (1) (b); or

(b) the supply of a related pharmaceutical benefit that is prescribed in a medication chart in accordance with paragraph 19 (1) (b).

35 Medication charts — acknowledging receipt of infusion or related pharmaceutical benefit

(1) If the supply of an infusion is prescribed to an eligible public hospital patient in accordance with paragraph 14 (1) (b), the treating medical practitioner, or a person employed or engaged by the participating hospital authority, must record on the patient's medication chart the date that the infusion was supplied to the patient.

(2) If the supply of a related pharmaceutical benefit is prescribed to an eligible public hospital patient in accordance with paragraph 19 (1) (b), the treating medical practitioner, or a person employed or engaged by the participating hospital authority, must record on the patient's medication chart the date that the pharmaceutical benefit was supplied to the patient.

Part 4 Claims and payment

Division 1 Claims for payment

36 How claims to be made

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

(a) an approved supplier;

(b) an HSD hospital authority.

(2) If a non-approved public hospital authority supplies an infusion that contains trastuzumab under this Special Arrangement, the State or Territory responsible for the hospital may make an off-line claim for payment in accordance with section 40.

37 Modified references for claim by HSD hospital authority

The rules made by the Minister under subsection 99AAA (8) of the Act apply to a claim made by an HSD hospital authority as follows:

(a) a reference to an approved supplier or an approved hospital authority includes a reference to an HSD hospital authority;

(b) a reference to a number allotted to an approval under regulation 8A of the Regulations includes a reference to a number allotted to an approval under section 52 of the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010*.

38 Modified requirements for supply from medication chart

(1) This section applies to a claim, made by a participating hospital authority, for:

(a) supply of an infusion that was prescribed in an infusion medication chart; or

(b) supply of a related pharmaceutical benefit that was prescribed in a medication chart.

(2) The requirements in the rules determined by the Minister under subsection 99AAA (8) of the Act are modified as follows:

(a) the participating hospital authority is not required to supply the medication chart with the claim;

(b) the participating hospital authority must keep an electronic version of the information supplied with the claim for 1 year from the day that the infusion or related pharmaceutical benefit is supplied;

(c) if requested by the Chief Executive Medicare, the participating hospital authority must give the Chief Executive Medicare a copy of:

(i) the medication chart; and

(ii) the information supplied with the claim.

39 Modified requirements for supply of infusion

For a claim for supply of an infusion, the requirements in the rules determined by the Minister under subsection 99AAA (8) of the Act are modified as follows:

(a) a reference to a pharmaceutical benefit includes a reference to an infusion;

(b) a reference to an authority prescription in the rules includes a reference to an authority prescription within the meaning given by section 3 of this Special Arrangement;

(c) the claim must include:

(i) a drug code for each chemotherapy drug in the infusion, being the code for the drug published in the *Schedule of Pharmaceutical Benefits* published by the Department; and

(ii) the dose of each chemotherapy drug in the infusion; and

(iii) for a claim submitted on or after 1 April 2012 — the authority approval number or Streamlined Authority Code in relation to each circumstance, if any, for which authorisation of the prescription or medication chart is required;

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

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

(ii) the brand of the supplied pharmaceutical item.

40 Off-line claim by State or Territory

To make an off-line claim, a State or Territory must:

(a) lodge with the Human Services Department one claim per calendar month for payment for all infusions containing trastuzumab supplied by all non-approved public hospital authorities within the State or Territory; and

(b) submit the claim within 3 months (or such longer period as the Chief Executive Medicare allows) after the end of the calendar month to which the claim relates; and

(c) include in the claim the following information for each supply of an infusion containing trastuzumab:

(i) the hospital provider number of the hospital that supplied the infusion;

(ii) the authority approval number allotted to the prescription by the Chief Executive Medicare;

(iii) whether the supply is the original or repeated supply;
(iv) the date on which the infusion was supplied;
(v) the dose of trastuzumab in the infusion.

Division 2 Payment of claim

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

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

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

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

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

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

44 Payment of State or Territory for supply of trastuzumab by non-approved public hospital authorities

A State or Territory that makes a claim in accordance with section 40 for the supply of an infusion containing trastuzumab is entitled to be paid by the Commonwealth 99.2% of the dispensed price for the dose of trastuzumab.

45 Method of working out dispensed price

Infusion

(1) The dispensed price for the supply of an infusion is the sum of:

(a) the dispensed prices of the doses of chemotherapy drugs in the infusion; and

(b) if the supply is a repeated supply — an amount equivalent to the amount that may be charged under subsection 87 (2) of the Act for the supply of a pharmaceutical benefit to the eligible patient.

(2) The dispensed price for a dose of a chemotherapy drug is to be worked out under Division 3.

Related pharmaceutical benefit

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

Rounding

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

46 No separate entitlement to payment for supply of diluent

(1) If a supplier adds a pharmaceutical benefit to an infusion supplied under this Special Arrangement as a diluent, no amount is payable under Part VII of the Act for supply of the pharmaceutical benefit.

(2) Subsection (1) applies regardless of whether the pharmaceutical benefit added as a diluent is one to which this Special Arrangement applies.

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

Division 3 Dispensed price of chemotherapy drug

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

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

(a) the base price for the dose worked out under subsection (2);

(b) the distribution fee;

(c) the dispensing fee;

(d) the preparation fee;

Federal Register of Legislative Instruments F2011L02491

(e) the diluent fee.

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

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

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

Example

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

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

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

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

(b) the mark-up for the chemotherapy pharmaceutical benefit worked out under:

(i) if the chemotherapy pharmaceutical benefit does not have trastuzumab — section 48; or

(ii) if the chemotherapy pharmaceutical benefit has trastuzumab — section 49.

Note The reference price and the ex-manufacturer price for a quantity of 1 are for the form of the chemotherapy pharmaceutical benefit mentioned in Part 1 of Schedule 1, which is not necessarily the same quantity as the quantity in a manufacturer's pack.

For example, if a chemotherapy pharmaceutical benefit has a form of 'Injection 500 mg in 10 mL', and a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price of the pack would be divided by 3 to obtain the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

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

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

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

Federal Register of Legislative Instruments F2011L02491

where:

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

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

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

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

Item	Ex-manufacturer price for maximum multiple of pharmaceutical benefit	Mark-up for maximum multiple
1	≤ $30	15% of ex-manufacturer price for maximum multiple of pharmaceutical benefit
2	> $30, ≤ $45	$4.50
3	> $45, ≤ $180	10% of ex-manufacturer price for maximum multiple of pharmaceutical benefit
4	> $180, ≤ $450	$18
5	> $450, ≤ $1 750	4% of ex-manufacturer price for maximum multiple of pharmaceutical benefit
6	> $1 750	$70

49 Mark-up for chemotherapy pharmaceutical benefit that has trastuzumab

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

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

where:

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

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

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

Federal Register of Legislative Instruments F2011L02491

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

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

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

(1) For a dose of a chemotherapy drug in an infusion supplied by an approved hospital authority of a private hospital to an eligible patient, the ***dispensed price*** is the sum of the following amounts:

(a) the base price for the dose worked out under subsection (2);

(b) for a drug other than trastuzumab — the distribution fee;

(c) the dispensing fee;

(d) the preparation fee;

(e) the diluent fee.

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

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

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

Example

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

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

Federal Register of Legislative Instruments F2011L02491

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

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

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

Note The reference price and the ex-manufacturer price for a quantity of 1 are for the form of the chemotherapy pharmaceutical benefit mentioned in Part 1 of Schedule 1, which is not necessarily the same quantity as the quantity in a manufacturer's pack.

For example, if a chemotherapy pharmaceutical benefit has a form of 'Injection 500 mg in 10 mL', and a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price of the pack would be divided by 3 to obtain the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

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

(1) For a dose of a chemotherapy drug in an infusion supplied by a public hospital authority to an eligible patient, the ***dispensed price*** is the sum of the following amounts:

(a) the base price for the dose worked out under subsection (2);

(b) the preparation fee.

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

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

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

Example

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

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

Federal Register of Legislative Instruments F2011L02491

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

Note The reference price and the ex-manufacturer price for a quantity of 1 are for the form of the chemotherapy pharmaceutical benefit mentioned in Part 1 of Schedule 1, which is not necessarily the same quantity as the quantity in a manufacturer's pack.

For example, if a chemotherapy pharmaceutical benefit has a form of 'Injection 500 mg in 10 mL', and a manufacturer's pack contains 3 lots of 'Injection 500 mg in 10 mL', the ex-manufacturer price of the pack would be divided by 3 to obtain the ex-manufacturer price for a quantity of 1 of the chemotherapy pharmaceutical benefit.

Division 4 Dispensed price of related pharmaceutical benefit

52 Dispensed price for supply of related pharmaceutical benefit

(1) For a related pharmaceutical benefit supplied by a participating hospital authority to an eligible patient, the ***dispensed price*** is as follows:

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

(b) if the quantity of the related pharmaceutical benefit that is ordered and supplied is less than the quantity contained in the manufacturer's pack — the amount worked out under section 53;

(c) if the quantity of the related pharmaceutical benefit that is ordered and supplied is more than the quantity contained in the manufacturer's pack — the sum of:

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

(ii) the amount worked out under section 53 for any remainder.

(2) However, if there are 2 or more related pharmaceutical benefits that are different brands of the same pharmaceutical item, the dispensed price of those pharmaceutical benefits is to be based on the pharmaceutical benefit with the lowest ex-manufacturer price.

Federal Register of Legislative Instruments F2011L02491

53 Quantity less than manufacturer's pack

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

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

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

Part 5 Patient contributions

54 Supply of infusion by approved pharmacist or approved medical practitioner

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

Patient co-payment for original supply

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

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

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

Special patient contribution for Schedule 5 pharmaceutical benefit

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

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

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

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

Patient co-payment for original supply

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

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

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

Special patient contribution for Schedule 5 pharmaceutical benefit

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

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

56 Supply of infusion by non-approved public hospital authority

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

Patient co-payment for original supply

(2) For an original supply of an infusion, the hospital authority may charge the eligible patient the relevant amount specified as the maximum value of a supply of out-patient medication in the determination made under subsection 84BA (2) of the Act, as in force on the date of the supply of the infusion.

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

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

Special patient contribution for Schedule 5 pharmaceutical benefit

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

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

57 Supply of related pharmaceutical benefit by participating hospital authority

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

Patient co-payment

(2) The participating hospital authority may charge the eligible patient an amount not exceeding the amount that the patient could have been required to pay under subsection 87 (2) of the Act if the patient had obtained the related pharmaceutical benefit from an approved pharmacist.

Special patient contribution for Schedule 5 pharmaceutical benefit

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

58 Special patient contribution for Schedule 5 pharmaceutical benefit

(1) The amount an eligible patient may be charged for a pharmaceutical benefit mentioned in Schedule 5 is worked out by subtracting the amount mentioned for the pharmaceutical benefit in the 'Approved Ex-manufacturer Price' column in Schedule 5 from the amount mentioned for the pharmaceutical benefit in the 'Claimed Ex-manufacturer Price' column in Schedule 5.

(2) However, the amounts mentioned in the 'Approved Ex-manufacturer price' and 'Claimed Ex-manufacturer price' columns must be adjusted proportionally if:

(a) for a chemotherapy pharmaceutical benefit — the quantity or number of units of the pharmaceutical benefit used to make the infusion is more or less than the number mentioned in the 'Quantity or Number of Units' column; and

(b) for a related pharmaceutical benefit — the quantity or number of units of the pharmaceutical benefit supplied is more or less than the number mentioned in the 'Quantity or Number of Units' column.

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

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

(a) subsection 54 (2);

(b) subsection 55 (2);

(c) subsection 56 (2);

(d) subsection 57 (2).

Part 6 Transitional

60 Prescriptions for general supply

(1) This section applies if:

(a) a prescription for a pharmaceutical benefit was written before the commencement of this Special Arrangement; and

(b) the pharmaceutical benefit was not supplied before the commencement of this Special Arrangement; and

(c) on 30 November 2011 the pharmaceutical benefit was available for general supply on the Pharmaceutical Benefits Scheme; and

(d) under section 13 of this Special Arrangement, the pharmaceutical benefit is not available for general supply on the Pharmaceutical Benefits Scheme.

(2) Despite section 13 of this Special Arrangement, the pharmaceutical benefit may be supplied as if it continued to be available for general supply on the Pharmaceutical Benefits Scheme in accordance with the Act, and the instruments made under the Act that applied to the pharmaceutical benefit, as in force on 30 November 2011.

(3) However, if the pharmaceutical benefit is no longer determined as a pharmaceutical benefit under section 85 of the Act on the date of proposed supply:

(a) the pharmaceutical benefit must not be supplied; and

(b) a substitute benefit within the meaning of subsection 103 (2A) of the Act may be supplied if:

(i) immediately before the determination under section 85 was revoked, the *Schedule of Pharmaceutical Benefits* issued by the Department stated that the prescribed pharmaceutical benefit and the substitute benefit were equivalent; and

(ii) the requirements of paragraphs 103 (2A) (a), (c) and (d) of the Act are met.

(4) Subsection (2) stops having effect on 1 April 2012.

Schedule 1 Chemotherapy pharmaceutical benefits and chemotherapy drugs

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

Part 1 Chemotherapy pharmaceutical benefits and related information

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Arsenic	Injection concentrate containing arsenic trioxide 10 mg in 10 mL	Injection	Phenasen	PL	MP	C3150 C3891	D
Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL	Injection	Avastin	RO	MP	C3430 C3431 C3894 C3896	D
	Solution for I.V. infusion 400 mg in 16 mL	Injection	Avastin	RO	MP	C3430 C3431 C3894 C3896	D
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	Hospira Pty Limited	HH	MP	C1139 C1198	D
Bortezomib	Powder for injection 3.5 mg (with any determined brand of sodium chloride injection as the required solvent)	Injection	Velcade	JC	MP	C3762 C3763 C3764 C3765 C3766 C3767	
Carboplatin	Solution for I.V. injection 150 mg in 15 mL	Injection	Carboplatin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution for I.V. injection 450 mg in 45 mL	Injection	Carboplatin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D
	Solution for I.V. injection 50 mg in 5 mL	Injection	Carboplatin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D
Cetuximab	Solution for I.V. infusion 100 mg in 20 mL	Injection	Erbitux	SG	MP	C2713 C2714 C2715 C3843 C3844 C3903 C3904 C3919 C3920 C3921	D
	Solution for I.V. infusion 500 mg in 100 mL	Injection	Erbitux	SG	MP	C2713 C2714 C2715 C3843 C3844 C3903 C3904 C3919 C3920 C3921	D
Cisplatin	I.V. injection 10 mg in 10 mL	Injection	Pfizer Australia Pty Ltd	PF	MP		D
	I.V. injection 100 mg in 100 mL	Injection	Cisplatin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D
	I.V. injection 50 mg in 50 mL	Injection	Hospira Pty Limited	HH	MP		D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Pfizer Australia Pty Ltd	PF	MP		D
Cladribine	Injection 10 mg in 5 mL	Injection	Litak	OA	MP	C3180	D
	Solution for I.V. infusion 10 mg in 10 mL single use vial	Injection	Leustatin	JC	MP	C3180	D
Cyclophosphamide	Powder for injection 1 g (anhydrous)	Injection	Endoxan	BX	MP		PB
	Powder for injection 2 g (anhydrous)	Injection	Endoxan	BX	MP		PB
	Powder for injection 500 mg (anhydrous)	Injection	Endoxan	BX	MP		PB
Cytarabine	Injection 100 mg in 5 mL vial	Injection	Pfizer Australia Pty Ltd	PF	MP		D
Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	Injection	Taxotere	SW	MP	C3186 C3884 C3888 C3890 C3892 C3893 C3916 C3918	D
	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	Injection	Taxotere	SW	MP	C3186 C3884 C3888 C3890 C3892 C3893 C3916 C3918	D
	Powder for I.V. infusion 20 mg with solvent	Injection	Docetaxel SUN	ZF	MP	C3186 C3884 C3890 C3893	D
	Powder for I.V. infusion 80 mg with solvent	Injection	Docetaxel SUN	ZF	MP	C3186 C3884 C3890 C3893	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution concentrate for I.V. infusion 140 mg in 7 mL	Injection	Oncotaxel 140	TA	MP	C3186 C3884 C3888 C3890 C3892 C3893 C3916 C3918	D
	Solution concentrate for I.V. infusion 160 mg in 16 mL	Injection	DBL Docetaxel Concentrated Injection	HH	MP	C3186 C3884 C3888 C3890 C3893 C3916 C3918	D
	Solution concentrate for I.V. infusion 20 mg in 1 mL	Injection	Oncotaxel 20	TA	MP	C3186 C3884 C3888 C3890 C3892 C3893 C3916 C3918	D
			Taxotere	SW	MP	C3186 C3884 C3888 C3890 C3892 C3893 C3916 C3918	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution concentrate for I.V. infusion 20 mg in 2 mL	Injection	DBL Docetaxel Concentrated Injection	HH	MP	C3186 C3884 C3888 C3890 C3893 C3916 C3918	D
			Docetaxel Ebewe	HX	MP	C3186 C3884 C3888 C3890 C3893 C3916	D
			Docetaxel Sandoz	SZ	MP	C3186 C3884 C3888 C3890 C3893 C3916 C3918	D
	Solution concentrate for I.V. infusion 80 mg in 4 mL	Injection	Oncotaxel 80	TA	MP	C3186 C3884 C3888 C3890 C3892 C3893 C3916 C3918	D
			Taxotere	SW	MP	C3186 C3884 C3888	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
						C3890 C3892 C3893 C3916 C3918	
	Solution concentrate for I.V. infusion 80 mg in 8 mL	Injection	DBL Docetaxel Concentrated Injection	HH	MP	C3186 C3884 C3888 C3890 C3893 C3916 C3918	D
			Docetaxel Ebewe	HX	MP	C3186 C3884 C3888 C3890 C3893 C3916	D
			Docetaxel Sandoz	SZ	MP	C3186 C3884 C3888 C3890 C3893 C3916 C3918	D
Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial	Injection/ intravesical	Adriamycin Solution	PF	MP		D
			Doxorubicin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
	Solution for I.V. injection or intravesical administration	Injection/	Doxorubicin Ebewe	SZ	MP		D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	containing doxorubicin hydrochloride 100 mg in 50 mL single dose vial	intravesical					
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 20 mg in 10 mL single dose vial	Injection/ intravesical	Adriamycin Solution	PF	MP		D
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial	Injection/ intravesical	Adriamycin	PF	MP		D
			Doxorubicin Ebewe	SZ	MP		D
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 50 mg in 25 mL single dose vial	Injection/ intravesical	Adriamycin Solution	PF	MP		D
			Doxorubicin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
Doxorubicin - Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	JC	MP	C1568 C1795 C1796 C3905 C3910 C3911	D
	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 50 mg in 25 mL	Injection	Caelyx	JC	MP	C1568 C1795 C1796 C3905 C3910 C3911	D
Epirubicin	Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL	Injection/ intravesical	Epirubicin Ebewe	SZ	MP		D
			Pharmorubicin Solution	PF	MP		D
	Solution for injection containing epirubicin hydrochloride 100 mg in 50 mL	Injection/ intravesical	Epirubicin Ebewe	SZ	MP		D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Hospira Pty Limited	HH	MP		D
	Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL	Injection/ intravesical	Pharmorubicin Solution	PF	MP		D
	Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL	Injection/ intravesical	DBL Epirubicin Hydrochloride Injection	HH	MP		D
			Epirubicin Ebewe	SZ	MP		D
	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL	Injection/ intravesical	Epirubicin Ebewe	SZ	MP		D
			Hospira Pty Limited	HH	MP		D
			Pharmorubicin Solution	PF	MP		D
Etoposide	Powder for I.V. infusion 1 g (as phosphate)	Injection	Etopophos	BQ	MP		PB
	Powder for I.V. infusion 100 mg (as phosphate)	Injection	Etopophos	BQ	MP		PB
	Solution for I.V. infusion 100 mg in 5 mL vial	Injection	Etoposide Ebewe	SZ	MP		PB
			Hospira Pty Limited	HH	MP		PB
Fludarabine	Powder for I.V. injection containing fludarabine phosphate 50 mg	Injection	Farine	WQ	MP	C3887	PB
			Fludara	GZ	MP	C3887	PB
			Fludarabine Actavis	TA	MP	C3887	PB
	Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL	Injection	Fludarabine Ebewe	SZ	MP	C3887	PB
Fluorouracil	Injection 1000 mg in 20 mL	Injection	DBL Fluorouracil Injection BP	HH	MP	C3923 C3924	D
			Fluorouracil Ebewe	SZ	MP	C3923 C3924	D
	Injection 2500 mg in 50 mL	Injection	DBL Fluorouracil Injection BP	HH	MP	C3923 C3924	D
			Fluorouracil Ebewe	SZ	MP	C3923 C3924	D
	Injection 500 mg in 10 mL	Injection	Fluorouracil Ebewe	SZ	MP	C3923 C3924	D
			Hospira Pty Limited	HH	MP	C3923	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
						C3924	
	Injection 5000 mg in 100 mL	Injection	Fluorouracil Ebewe	SZ	MP	C3923 C3924	D
Fotemustine	Powder for injection 208 mg with solvent	Injection	Muphoran	SE	MP	C3181	D
Gemcitabine	Powder for I.V. infusion 1 g (as hydrochloride)	Injection	DBL Gemcitabine for Injection	HH	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemcitabine Actavis	TA	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemcitabine Ebewe	SZ	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890	D

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Gemcitabine Kabi	PK	MP	C3906 C3913 C3914 C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914 C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914 C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906	D
			Gemcitabine Sun	ZF	MP		D
			Gemcite	ZP	MP		D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Gemplan	WQ	MP	C3913 C3914 C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemzar	LY	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
	Powder for I.V. infusion 2 g (as hydrochloride)	Injection	DBL Gemcitabine for Injection	HH	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Gemcitabine Kabi	PK	MP	C3914 C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
	Powder for I.V. infusion 200 mg (as hydrochloride)	Injection	DBL Gemcitabine for Injection	HH	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemcitabine Actavis	TA	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Gemcitabine Ebewe	SZ	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemcitabine Kabi	PK	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemcitabine Sun	ZF	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemcite	ZP	MP	C1193	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
						C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	
			Gemplan	WQ	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
			Gemzar	LY	MP	C1193 C1194 C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914	D
	Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL	Injection	Gemcitabine Ebewe	SZ	MP	C1193 C1194	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL	Injection	Gemcitabine Ebewe	SZ	MP	C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914 C1193 C1194	D
	Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL	Injection	Gemcitabine Ebewe	SZ	MP	C1740 C2069 C2141 C3889 C3890 C3906 C3913 C3914 C1193 C1194	D
Idarubicin	Solution for I.V. injection containing idarubicin hydrochloride 10 mg in 10 mL	Injection	Idarubicin Ebewe	SZ	MP	C1006	PB
			Zavedos Solution	PF	MP	C1006	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
	Solution for I.V. injection containing idarubicin hydrochloride 5 mg in 5 mL	Injection	Idarubicin Ebewe	SZ	MP	C1006	PB
			Zavedos Solution	PF	MP	C1006	PB
Ifosfamide	Powder for I.V. injection 1 g in single dose vial	Injection	Holoxan	BX	MP	C1325 C1327	D
	Powder for I.V. injection 2 g in single dose vial	Injection	Holoxan	BX	MP	C1325 C1327	D
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Camptosar	PF	MP	C3184	D
			Hospira Pty Limited	HH	MP	C3184	D
			Irinotecan Actavis	TA	MP	C3184	D
			Irinotecan Alphapharm	AF	MP	C3184	D
			Irinotecan Ebewe	SZ	MP	C3184	D
			Irinotecan Kabi	PK	MP	C3184	D
			Omegapharm Irinotecan	OE	MP	C3184	D
			Tecan	WQ	MP	C3184	D
	I.V. injection containing irinotecan hydrochloride trihydrate 300 mg in 15 mL	Injection	Camptosar	PF	MP	C3184	D
			Irinotecan Ebewe	SZ	MP	C3184	D
	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL	Injection	Camptosar	PF	MP	C3184	D
			Hospira Pty Limited	HH	MP	C3184	D
			Irinotecan Actavis	TA	MP	C3184	D
			Irinotecan Alphapharm	AF	MP	C3184	D
			Irinotecan Ebewe	SZ	MP	C3184	D
			Irinotecan Kabi	PK	MP	C3184	D
			Omegapharm Irinotecan	OE	MP	C3184	D
			Tecan	WQ	MP	C3184	D
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Injection	Hospira Pty Limited	HH	MP	C3184	D
			Irinotecan Actavis 500	TA	MP	C3184	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Irinotecan Ebewe	SZ	MP	C3184	D
Methotrexate	Injection 5 mg in 2 mL vial	Injection	Hospira Pty Limited	HH	MP		
	Injection 50 mg in 2 mL vial	Injection	Hospira Pty Limited	HH	MP		
			Pfizer Australia Pty Ltd	PF	MP		
	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial	Injection	Hospira Pty Limited	HH	MP		PB
			Methotrexate Ebewe	SZ	MP		PB
	Solution concentrate for I.V. infusion 500 mg in 20 mL vial	Injection	Hospira Pty Limited	HH	MP		PB
	Solution concentrate for I.V. infusion 5000 mg in 50 mL vial	Injection	Methotrexate Ebewe	SZ	MP		PB
Mitozantrone	Injection 10 mg (as hydrochloride) in 5 mL	Injection	Pfizer Australia Pty Ltd	PF	MP		D
	Injection 20 mg (as hydrochloride) in 10 mL	Injection	Hospira Pty Limited	HH	MP		D
			Mitozantrone Ebewe	SZ	MP		D
			Onkotrone	BX	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D
	Injection 25 mg (as hydrochloride) in 12.5 mL	Injection	Onkotrone	BX	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D
Oxaliplatin	Powder for I.V. infusion 100 mg	Injection	Hospira Pty Limited	HH	MP	C3900 C3901 C3930 C3939	D
			Oxalatin	ZP	MP	C3900 C3901 C3930 C3939	D
			Oxaliplatin Actavis	TA	MP	C3900 C3901 C3930 C3939	D
			Oxaliplatin Alphapharm	AF	MP	C3900 C3901 C3930 C3939	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Oxaliplatin Ebewe	SZ	MP	C3900 C3901 C3930 C3939	D
			Oxaliplatin Link	PK	MP	C3900 C3901 C3930 C3939	D
			Winthrop Oxaliplatin	WA	MP	C3900 C3901 C3930 C3939	D
			Xalox	WQ	MP	C3900 C3901 C3930 C3939	D
	Powder for I.V. infusion 50 mg	Injection	Hospira Pty Limited	HH	MP	C3900 C3901 C3930 C3939	D
			Oxalatin	ZP	MP	C3900 C3901 C3930 C3939	D
			Oxaliplatin Actavis	TA	MP	C3900 C3901 C3930 C3939	D
			Oxaliplatin Alphapharm	AF	MP	C3900 C3901 C3930	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Oxaliplatin Ebewe	SZ	MP	C3939 C3900 C3901 C3930	D
			Oxaliplatin Link	PK	MP	C3939 C3900 C3901 C3930	D
			Xalox	WQ	MP	C3939 C3900 C3901 C3930	D
	Solution concentrate for I.V. infusion 100 mg in 20 mL	Injection	DBL Oxaliplatin Concentrate	HH	MP	C3939 C3900 C3901 C3930	D
			Eloxatin	SW	MP	C3939 C3900 C3901 C3930	D
			Oxaliplatin Kabi	PK	MP	C3939 C3900 C3901 C3930	D
			Oxaliplatin SUN	ZF	MP	C3939 C3900 C3901 C3930	D
	Solution concentrate for I.V. infusion 200 mg in 40 mL	Injection	Eloxatin	SW	MP	C3939 C3900 C3901	D

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Oxaliplatin SUN	ZF	MP	C3930 C3939 C3900 C3901	D
	Solution concentrate for I.V. infusion 50 mg in 10 mL	Injection	DBL Oxaliplatin Concentrate	HH	MP	C3930 C3939 C3900 C3901	D
			Eloxatin	SW	MP	C3930 C3939 C3900 C3901	D
			Oxaliplatin Kabi	PK	MP	C3930 C3939 C3900 C3901	D
			Oxaliplatin SUN	ZF	MP	C3930 C3939 C3900 C3901	D
Paclitaxel	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	Injection	Anzatax	HH	MP	C3930 C3939 C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Actavis	TA	MP	C3186 C3890 C3893	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Paclitaxel Ebewe	SZ	MP	C3902 C3917 C3918 C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Kabi	PK	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Plaxel	WQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Taxol	BQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
	Solution concentrate for I.V. infusion 150 mg in 25 mL	Injection	Anzatax	HH	MP	C3186 C3890 C3893 C3902	D

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Paclitaxel Actavis	TA	MP	C3917 C3918 C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Ebewe	SZ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Plaxel	WQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
	Solution concentrate for I.V. infusion 30 mg in 5 mL	Injection	Anzatax	HH	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Actavis	TA	MP	C3186 C3890 C3893 C3902 C3917	D

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Paclitaxel Ebewe	SZ	MP	C3918 C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Kabi	PK	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Plaxel	WQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Taxol	BQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
	Solution concentrate for I.V. infusion 300 mg in 50 mL	Injection	Anzatax	HH	MP	C3186 C3890 C3893 C3902 C3917 C3918	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
			Paclitaxel Actavis	TA	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Ebewe	SZ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Paclitaxel Kabi	PK	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Plaxel	WQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
			Taxol	BQ	MP	C3186 C3890 C3893 C3902 C3917 C3918	D
Paclitaxel, nanoparticle	Powder for I.V. injection containing 100 mg paclitaxel	Injection	Abraxane	TS	MP	C3897	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
albumin-bound Pemetrexed	Powder for I.V. infusion 100 mg (as disodium heptahydrate)	Injection	Alimta	LY	MP	C2957 C2958 C3885 C3886	D
	Powder for I.V. infusion 500 mg (as disodium heptahydrate)	Injection	Alimta	LY	MP	C2957 C2958 C3885 C3886	D
Raltitrexed	Powder for I.V. infusion 2 mg in single use vial	Injection	Tomudex	HH	MP	C3185	D
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Mabthera	RO	MP	C1744 C1745 C2068 C2386 C3908 C3909 C3912 C3915 C3931 C3932	D
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	RO	MP	C1744 C1745 C2068 C2386 C3908 C3909 C3912 C3915 C3931 C3932	D
Topotecan	Powder for I.V. infusion 4 mg (as hydrochloride)	Injection	Hycamtin	GK	MP	C3186	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only
Trastuzumab	Powder for I.V. infusion 150 mg	Injection	Herceptin	RO	MP	C3926 C3927 C3928 C3929	D
	Powder for I.V. infusion 60 mg	Injection	Herceptin	RO	MP	C3926 C3927 C3928 C3929	D
Vinblastine	Solution for I.V. injection containing vinblastine sulfate 10 mg in 10 mL	Injection	Hospira Pty Limited	HH	MP		D
Vincristine	I.V. injection containing vincristine sulfate 1 mg in 1 mL	Injection	Hospira Pty Limited	HH	MP		D
			Pfizer Australia Pty Ltd	PF	MP		D
Vinorelbine	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	Injection	Hospira Pty Limited	HH	MP	C3890 C3907	PB
			Navelbine	FB	MP	C3890 C3907	PB
			Vinorelbine Ebewe	SZ	MP	C3890 C3907	PB
	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	Injection	Hospira Pty Limited	HH	MP	C3890 C3907	PB
			Navelbine	FB	MP	C3890 C3907	PB
			Vinorelbine Ebewe	SZ	MP	C3890 C3907	PB
			Vinorelbine Kabi	PK	MP	C3890 C3907	PB

Part 2 Chemotherapy drugs and related information

Listed Drug	Purposes	Maximum Amount	Number of Repeats
Arsenic		18	89
Bevacizumab		900	11
Bleomycin		30000	11
Bortezomib	P3762 P3763 P3765 P3766	3000	15
	P3764 P3767	3000	11
Carboplatin		900	5
Cetuximab	P3844 P3904	550	11
	P2715 P3921	550	5
	P2713 P2714 P3843 P3903 P3919 P3920	880	0
Cisplatin		220	14
Cladribine		17	6
Cyclophosphamide		2800	17
Cytarabine		7000	15
Docetaxel		250	5
Doxorubicin		135	11
Doxorubicin - Pegylated Liposomal		100	5
Epirubicin		220	5
Etoposide		440	14
Fludarabine		55	29
Fluorouracil	P3924	1000	23
	P3923	5500	11
Fotemustine		220	8
Gemcitabine		3000	17
Idarubicin		30	5
Ifosfamide		4000	19
Irinotecan		800	11
Methotrexate		250	5
	P3925	20000	0
Mitozantrone		30	5
Oxaliplatin		300	11
Paclitaxel		450	3
Paclitaxel, nanoparticle albumin-bound		580	5
Pemetrexed		1100	5
Raltitrexed		7	8
Rituximab	P2068 P2386 P3912 P3915	800	7
	P1744 P1745 P3908 P3909	800	3
	P3931	1100	5

Listed Drug	Purposes	Maximum Amount	Number of Repeats
	P3932		
Topotecan		3500	17
Trastuzumab	P3929	250	9
	P3927	500	0
	P3928	750	3
	P3926	1000	0
Vinblastine		20	17
Vincristine		2	7
Vinorelbine		70	7

Federal Register of Legislative Instruments F2011L02491

Schedule 2 Related pharmaceutical benefits

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

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
"BCG Immunotherapeutic" (Bacillus Calmette-Guérin/ Connaught strain)	Powder for intravesical administration containing 6.6 to 19.2 x 10^{8} CFU	Intravesical	ImmuCyst	SW	EMP	C1419		3	1	
"BCG-Tice" (Bacillus Calmette-Guérin/ Tice strain)	Vial containing powder for intravesical administration approximately 5 x 10^{8} CFU	Intravesical	OncoTICE	MK	EMP	C1290		3	1	
Aprepitant	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	Oral	Emend	MK	EMP	C3619 C3620 C3621		1	5	
Folinic acid	Tablet containing calcium folinate equivalent to 15 mg folinic acid	Oral	Leucovorin Calcium (Hospira Pty Limited)	HH	EMP	C1028		10	0	
	Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL	Injection	Calcium Folinate Ebewe	SZ	EMP			5	5	
			Leucovorin Calcium (Hospira Pty Limited)	HH	EMP			5	5	
			Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	EMP			5	5	
	Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL	Injection	Calcium Folinate Ebewe	SZ	EMP			10	1	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	EMP			10	1	
	Injection containing calcium folinate equivalent to 300 mg folinic acid in 30 mL	Injection	Calcium Folinate Ebewe	SZ	EMP			4	1	
			Leucovorin Calcium (Hospira Pty Limited)	HH	EMP			4	1	
	Injection containing calcium folinate equivalent to 1000 mg folinic acid in 100 mL	Injection	Calcium Folinate Ebewe	SZ	EMP			1	1	
Granisetron	Tablet 2 mg (as hydrochloride)	Oral	Kytril	HH	EMP	C3050		2	0	
	Concentrated injection 3 mg (as hydrochloride) in 3 mL	Injection	Granisetron Kabi	PK	EMP	C3050		1	0	
			Kytril	HH	EMP	C3050		1	0	
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C3180 C3895 C3899	P3180 P3899	15	4	
			Roferon-A	RO	EMP	C3180 C3895 C3899	P3895	15	5	
	Injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C3895 C3899	P3899	5	4	
			Roferon-A	RO	EMP	C3895 C3899	P3895	5	5	
	Injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C3895 C3899	P3899	5	4	
			Roferon-A	RO	EMP	C3895 C3899	P3895	5	5	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	Roferon-A	RO	EMP	C3895 C3899	P3899	5	4	
			Roferon-A	RO	EMP	C3895 C3899	P3895	5	5	
Interferon Alfa-2b	Solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	MK	EMP	C3180 C3895 C3898	P3180	3	4	
			Intron A Redipen	MK	EMP	C3180 C3895 C3898	P3895 P3898	3	5	
	Solution for injection 30,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	Intron A Redipen	MK	EMP	C3895 C3898		3	5	
Mesna	Solution for I.V. injection 400 mg in 4 mL ampoule	Injection	Uromitexan	BX	EMP	C1618		15	5	
	Solution for I.V. injection 1 g in 10 mL ampoule	Injection	Uromitexan	BX	EMP	C1618		15	5	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	EMP	C3050		4	0	
			Ondansetron-DRLA	RZ	EMP	C3050		4	0	
			Ondaz	SZ	EMP	C3050		4	0	
			Onsetron 4	ZP	EMP	C3050		4	0	
			Zofran	GK	EMP	C3050		4	0	
	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	EMP	C3050		4	0	
			Ondansetron-DRLA	RZ	EMP	C3050		4	0	
			Ondaz	SZ	EMP	C3050		4	0	
			Onsetron 8	ZP	EMP	C3050		4	0	
			Zofran	GK	EMP	C3050		4	0	
	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT-DRLA	RZ	EMP	C3050		4	0	
	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT-DRLA	RZ	EMP	C3050		4	0	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Wafer 4 mg	Oral	Ondaz Zydis	SZ	EMP	C3050		4	0	
			Zofran Zydis	GK	EMP	C3050		4	0	
	Wafer 8 mg	Oral	Ondaz Zydis	SZ	EMP	C3050		4	0	
			Zofran Zydis	GK	EMP	C3050		4	0	
	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	Oral	Zofran syrup 50 mL	GK	EMP	C3050		1	0	
	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	Injection	Ondansetron Alphapharm	AF	EMP	C3050		1	0	
			Ondansetron-Claris	AE	EMP	C3050		1	0	
			Ondaz	SZ	EMP	C3050		1	0	
			Onsetron	ZP	EMP	C3050		1	0	
			Pfizer Australia Pty Ltd	PF	EMP	C3050		1	0	
			Zofran	GK	EMP	C3050		1	0	
	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	Injection	Ondansetron Alphapharm	AF	EMP	C3050		1	0	
			Ondansetron-Claris	AE	EMP	C3050		1	0	
			Ondaz	SZ	EMP	C3050		1	0	
			Onsetron	ZP	EMP	C3050		1	0	
			Pfizer Australia Pty Ltd	PF	EMP	C3050		1	0	
			Zofran	GK	EMP	C3050		1	0	
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	Aloxi	TS	EMP	C3545		1	0	
Tropisetron	Capsule 5 mg (as hydrochloride)	Oral	Navoban	NV	EMP	C3050		2	0	
	I.V. injection 5 mg (as hydrochloride) in 5 mL	Injection	Navoban	NV	EMP	C3050		1	0	

Federal Register of Legislative Instruments F2011L02491

Schedule 3 Responsible Person Codes

(section 6)

Code	Responsible Person	ABN
AE	AFT Pharmaceuticals Pty Ltd	29 105 636 413
AF	Alphapharm Pty Ltd	93 002 359 739
BQ	Bristol-Myers Squibb Australia Pty Ltd	33 004 333 322
BX	Baxter Healthcare Pty Ltd	43 000 392 781
FB	Pierre Fabre Medicament Australia Pty Ltd	30 098 999 850
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
HX	Sandoz Pty Ltd	60 075 449 553
JC	Janssen-Cilag Pty Ltd	47 000 129 975
LY	Eli Lilly Australia Pty Ltd	39 000 233 992
MK	Merck Sharp & Dohme (Australia) Pty Ltd	14 000 173 508
NV	Novartis Pharmaceuticals Australia Pty Limited	18 004 244 160
OA	Orphan Australia Pty Ltd	11 067 189 342
OE	Omegapharm Pty Ltd	86 128 078 151
PF	Pfizer Australia Pty Ltd	50 008 422 348
PK	Fresenius Kabi Australia Pty Limited	39 109 383 593
PL	The Trustee for Virgo Unit Trust (trading as Phebra)	77 695 661 635
RO	Roche Products Pty Ltd	70 000 132 865
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd	16 120 092 408
SE	Servier Laboratories (Aust.) Pty Ltd	54 004 838 500
SG	Merck Serono Australia Pty Ltd	72 006 900 830
SW	sanofi-aventis Australia Pty Ltd	31 008 558 807
SZ	Sandoz Pty Ltd	60 075 449 553
TA	Actavis Australia Pty Ltd	43 122 896 468
TS	Specialised Therapeutics Australia Pty Ltd	73 124 031 241
TX	Apotex Pty Ltd	52 096 916 148
WA	sanofi-aventis Australia Pty Ltd	31 008 558 807
WQ	Willow Pharmaceuticals Pty Ltd	80 118 534 704
ZF	Sun Pharmaceutical Industries (Australia) Pty Ltd	64 130 119 603
ZP	Spirit Pharmaceuticals Pty Ltd	67 109 225 747

Schedule 4 Circumstances and Purposes Codes

(sections 8 to 12, 22 and 24)

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
"BCG Immunotherapeutic" (Bacillus Calmette-Guérin/ Connaught strain)	C1419		Treatment of carcinoma in situ of the urinary bladder	
"BCG-Tice" (Bacillus Calmette-Guérin/ Tice strain)	C1290		Primary and relapsing superficial urothelial carcinoma of the bladder	
Aprepitant	C3619		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, in combination with a 5-hydroxytryptamine type 3 receptor antagonist and dexamethasone, where any 1 of the following chemotherapy agents are to be administered: (a) altretamine; (b) carmustine; (c) cisplatin, when a single dose constitutes a cycle of chemotherapy; (d) cyclophosphamide, at a dose of 1500 mg per square metre per day or greater; (e) dacarbazine; (f) procarbazine, when a single dose constitutes a cycle of chemotherapy; (g) streptozocin; and where treatment with aprepitant is limited to an initial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy	Compliance with Authority Required procedures – Streamlined Authority Code 3619

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
	C3620		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5-hydroxytryptamine type 3 receptor antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered, and where treatment with aprepitant is limited to an initial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy	Compliance with Authority Required procedures – Streamlined Authority Code 3620
	C3621		Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5-hydroxytryptamine type 3 receptor (5HT3) antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered: (a) arsenic trioxide; (b) azacitidine; (c) carboplatin; (d) cyclophosphamide, at a dose of less than 1500 mg per square metre per day; (e) cytarabine, at a dose of greater than 1 g per square metre per day; (f) dactinomycin; (g) daunorubicin; (h) doxorubicin; (i) epirubicin; (j) fotemustine; (k) idarubicin; (l) ifosfamide; (m) irinotecan; (n) melphalan; (o) methotrexate, at a dose of 250 mg to 1 g per square metre;	Compliance with Authority Required procedures - Streamlined Authority Code 3621

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			(p) oxaliplatin; (q) raltitrexed; and where treatment with aprepitant is limited to an initial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy, and where concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle	
Arsenic	C3150		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Induction and consolidation treatment of relapsed acute promyelocytic leukaemia (characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript) in a patient who is arsenic naive at induction	Compliance with Authority Required Procedures
	C3891		Where the patient is receiving treatment at/from a Public Hospital Induction and consolidation treatment of relapsed acute promyelocytic leukaemia (characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript) in a patient who is arsenic naive at induction	Compliance with Authority Required procedures - Streamlined Authority Code 3891
Bevacizumab	C3430		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Initial PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with previously untreated metastatic colorectal cancer with a World Health Organisation performance status of 0 or 1, where the patient's dose of bevacizumab does not exceed 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks	Compliance with Authority Required Procedures
	C3431		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Continuing PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with metastatic colorectal cancer who has who	Compliance with Authority Required Procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			has previously been issued with an authority prescription for bevacizumab and who does not have progressive disease and who remains on first-line chemotherapy, where the patient's dose of bevacizumab does not exceed 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks	
	C3894		Where the patient is receiving treatment at/from a Public Hospital Initial PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with previously untreated metastatic colorectal cancer with a World Health Organisation performance status of 0 or 1, where the patient's dose of bevacizumab does not exceed 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks, and where the patient's WHO performace status and body weight is recorded in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 3894
	C3896		Where the patient is receiving treatment at/from a Public Hospital Continuing PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with metastatic colorectal cancer who has previously received PBS-subsidised treatment with bevacizumab and who does not have progressive disease and who remains on first-line chemotherapy, where the patient's dose of bevacizumab does not exceed 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks, and where the patient's body weight is documented in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 3896
Bleomycin	C1139		Germ cell neoplasms	
	C1198		Lymphoma	
Bortezomib	C3762	P3762	Retreatment of a patient who has been previously treated with PBS-subsidised bortezomib Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of a patient with multiple myeloma who has progressive disease and who has been previously treated with	Compliance with modified Written Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			PBS-subsidised bortezomib. The patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause) Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria. If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to re-treatment with bortezomib) is defined as: (a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours If serum M protein and Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as: (c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (d) at least a 50% reduction in bone marrow plasma cells; or (e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or (g) normalization of corrected serum calcium to less than or equal to 2.65 mmol per L. The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment. Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised lenalidomide The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application - Supporting Information Form which includes details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			(3) diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously provided to the Chief Executive Medicare To enable confirmation by the Chief Executive Medicare, current diagnostic reports of at least one of the following are required: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. 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 for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (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; and (4) a signed patient acknowledgment	
	C3763	P3763	Continuing retreatment of a patient who has been previously treated with	Compliance with modified Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			PBS-subsidised bortezomib Continuing PBS-subsidised retreatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has received 4 treatment cycles of bortezomib in the current treatment course and who, at the time of application, has demonstrated at least a partial response to bortezomib If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as: (a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or (b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as: (c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (d) at least a 50% reduction in bone marrow plasma cells; or (e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or (g) normalisation of corrected serum calcium to less than or equal to	Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			2.65 mmol per L. For the purpose of assessing eligibility for continuing the current course of PBS-subsidised bortezomib treatment beyond 4 cycles, the patient must have achieved at least a partial response at the completion of cycle 4. The results of the response assessment must be included in a written application to the Chief Executive Medicare for further treatment. Where a response assessment is not submitted to the Chief Executive Medicare prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and subsequent applications The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and (3) diagnostic reports demonstrating the patient has achieved at least a partial response. Diagnostic reports must be no more than 1 month old at the time of application Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib No more than 2 cycles of treatment beyond the cycle at which a confirmed complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart	
	C3764	P3764	Continuing retreatment of a patient who has been previously treated with	Compliance with modified Written

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			PBS-subsidised bortezomib Continuing PBS-subsidised retreatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has received 8 treatment cycles with bortezomib in the current treatment course and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as: (a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or (b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as: (c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (d) at least a 50% reduction in bone marrow plasma cells; or (e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or	Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment Diagnostic reports must be within 1 month of the date of application. For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 8 cycles, the patient must have achieved at least a partial response at the completion of cycle 8. The results of the response assessment must be included in a written application to the Chief Executive Medicare for further treatment. Where a response assessment is not submitted to the Chief Executive Medicare prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and (3) diagnostic reports demonstrating the patient has achieved at least a partial response. No more than 2 cycles of treatment beyond the cycle at which the complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles per treatment course will not be approved	
	C3765	P3765	Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a	Compliance with modified Written Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances

			patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib; and
			where the following conditions apply:
			if serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
			(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
			(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours;
			if serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
			(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels;
			if serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
			(d) at least a 50% reduction in bone marrow plasma cells; or
			(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
			(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or
			(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L;
			the same parameters provided for the diagnosis of progressive disease are	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			used to demonstrate at least a partial response to treatment; a patient is eligible for continuing PBS-subsidised bortezomib treatment beyond 4 cycles if they have achieved at least a partial response at the completion of cycle 4, and the results of the response assessment are included in the application for authorisation of further treatment; where a response assessment is not submitted to the Chief Executive Medicare prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib; the authority application is made in writing not later than 6 months after the application for initial treatment and includes: (1) a completed copy of the appropriate Multiple Myeloma Authority Application - Supporting Information Form; and (2) diagnostic reports, which are no more than 1 month old at the time of application, demonstrating that the patient has achieved at least a partial response; patients who fail to demonstrate at least a partial response after 8 cycles are not eligible to receive further PBS-subsidised treatment with bortezomib; a patient is eligible to receive no more than 2 cycles of treatment beyond the cycle at which a complete response, confirmed by 2 determinations a minimum of 6 weeks apart, was first achieved	
	C3766	P3766	Initial treatment with PBS-subsidised bortezomib Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, 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	Compliance with modified Written Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			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 (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	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			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 Grade 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 lenalidomide; 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 Chief Executive Medicare, current diagnostic reports of at least 1 of the following are required:	

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			(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	
	C3767	P3767	Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 8 treatment cycles with bortezomib and who, at the time of application, has demonstrated at least a partial response	Compliance with modified Written Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances

			to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response; and
			where the following conditions apply:
			if serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
			(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
			(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours;
			if serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
			(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value;
			if serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
			(d) at least a 50% reduction in bone marrow plasma cells; or
			(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
			(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or
			(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L;
			the same parameters provided for the diagnosis of progressive disease are used to demonstrate at least a partial response to treatment;	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			a patient is eligible for continuing PBS-subsidised bortezomib treatment beyond 8 cycles if they have achieved at least a partial response at the completion of cycle 8, and the results of the response assessment are included in the application for authorisation of further treatment; where a response assessment is not submitted to the Chief Executive Medicare prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib; the authority application is made in writing not later than 10 months after the application for initial treatment and includes: (1) a completed copy of the appropriate Multiple Myeloma Authority Application - Supporting Information Form; and (2) diagnostic reports, which are no more than 1 month old at the time of application, demonstrating that the patient has achieved at least a partial response; a patient is eligible to receive no more than 2 cycles of treatment beyond the cycle at which a complete response, confirmed by 2 determinations a minimum of 6 weeks apart, was first achieved; PBS-subsidised treatment with bortezomib is limited to a maximum of 11 cycles per treatment course	
Cetuximab	C2713	P2713	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the Therapeutic Goods Administration-approved Product Information	Compliance with Authority Required procedures
	C2714	P2714	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx,	Compliance with Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated	
	C2715	P2715	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated	Compliance with Authority Required procedures
	C3843	P3843	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Initial PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with a World Health Organisation performance status of 2 or less and with K-RAS wild type metastatic colorectal cancer after failure of first-line chemotherapy	Compliance with Authority Required procedures
	C3844	P3844	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Continuing PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with K-RAS wild type metastatic colorectal cancer who has previously been issued with an authority prescription for cetuximab and who does not have progressive disease	Compliance with Authority Required procedures
	C3903	P3903	Where the patient is receiving treatment at/from a Public Hospital Initial PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with a World Health Organisation performance status of 2 or less and with K-RAS wild type metastatic colorectal cancer after failure of first-line chemotherapy	Compliance with Authority Required procedures - Streamlined Authority Code 3903
	C3904	P3904	Where the patient is receiving treatment at/from a Public Hospital Continuing PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with K-RAS wild type	Compliance with Authority Required procedures - Streamlined Authority Code 3904

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			metastatic colorectal cancer who has previously been issued with an authority prescription for cetuximab and who does not have progressive disease	
	C3919	P3919	Where the patient is receiving treatment at/from a Public Hospital Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the Therapeutic Goods Administration-approved Product Information	Compliance with Authority Required procedures - Streamlined Authority Code 3919
	C3920	P3920	Where the patient is receiving treatment at/from a Public Hospital Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated	Compliance with Authority Required procedures - Streamlined Authority Code 3920
	C3921	P3921	Where the patient is receiving treatment at/from a Public Hospital Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated	Compliance with Authority Required procedures - Streamlined Authority Code 3921
Cladribine	C3180		Hairy cell leukaemia	Compliance with Authority Required procedures - Streamlined Authority Code 3180
Docetaxel	C3186	P3186	Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound	Compliance with Authority Required procedures – Streamlined Authority Code 3186
	C3884	P3884	Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%, where docetaxel is used as first-line chemotherapy and administered in three weekly cycles	Compliance with Authority Required procedures – Streamlined Authority Code 3884
	C3888	P3888	Neoadjuvant treatment of a patient with a World Health Organisation performance status of 1 or less, with inoperable Stage III, IVa or IVb	Compliance with Authority Required procedures – Streamlined Authority

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil	Code 3888
	C3890	P3890	Locally advanced or metastatic non-small cell lung cancer	Compliance with Authority Required procedures – Streamlined Authority Code 3890
	C3892	P3892	Adjuvant treatment of operable breast cancer in combination with cyclophosphamide	Compliance with Authority Required procedures – Streamlined Authority Code 3892
	C3893	P3893	Advanced breast cancer after failure of prior therapy	Compliance with Authority Required procedures – Streamlined Authority Code 3893
	C3916	P3916	Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide	Compliance with Authority Required procedures – Streamlined Authority Code 3916
	C3918	P3918	Treatment of HER2 positive early breast cancer in combination with trastuzumab	Compliance with Authority Required procedures – Streamlined Authority Code 3918
Doxorubicin - Pegylated Liposomal	C1568		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen	Compliance with Authority Required procedures
	C1795		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane	Compliance with Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
	C1796		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Metastatic breast cancer, as monotherapy, where therapy with capecitabine or a taxane is contraindicated	Compliance with Authority Required procedures
	C3905		Where the patient is receiving treatment at/from a Public Hospital Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen	Compliance with Authority Required procedures – Streamlined Authority Code 3905
	C3910		Where the patient is receiving treatment at/from a Public Hospital Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane	Compliance with Authority Required procedures – Streamlined Authority Code 3910
	C3911		Where the patient is receiving treatment at/from a Public Hospital Metastatic breast cancer, as monotherapy, where therapy with capecitabine or a taxane is contraindicated	Compliance with Authority Required procedures – Streamlined Authority Code 3911
Fludarabine	C3887		B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease, and where: (1) Stage A progressive disease is defined by at least 1 of the following: — persistent rise in lymphocyte count with doubling time less than 12 months; — a downward trend in haemoglobin or platelets, or both; — more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; — constitutional symptoms attributable to disease; and (2) the diagnosis of chronic lymphocytic leukaemia has been established based on: (a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and (b) a clonal population of B-cells (CD5/CD19) documented by flow	Compliance with Authority Required procedures – Streamlined Authority Code 3887

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			cytometry	
Fluorouracil	C3923	P3923	For patients requiring administration of fluorouracil by intravenous infusion	
	C3924	P3924	For patients requiring administration of fluorouracil by intravenous injection	
Folinic acid	C1028		Antidote to folic acid antagonists	
Fotemustine	C3181		Metastatic malignant melanoma	Compliance with Authority Required procedures - Streamlined Authority Code 3181
Gemcitabine	C1193		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Locally advanced or metastatic adenocarcinoma of the pancreas	Compliance with Authority Required procedures
	C1194		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Locally advanced or metastatic non-small cell lung cancer	Compliance with Authority Required procedures
	C1740		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Locally advanced or metastatic bladder cancer, in combination with cisplatin	Compliance with Authority Required procedures
	C2069		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline	Compliance with Authority Required procedures
	C2141		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy	Compliance with Authority Required procedures
	C3889		Where the patient is receiving treatment at/from a Public Hospital Locally advanced or metastatic adenocarcinoma of the pancreas	Compliance with Authority Required procedures - Streamlined Authority Code 3889

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
	C3890		Where the patient is receiving treatment at/from a Public Hospital Locally advanced or metastatic non-small cell lung cancer	Compliance with Authority Required procedures - Streamlined Authority Code 3890
	C3906		Where the patient is receiving treatment at/from a Public Hospital Locally advanced or metastatic bladder cancer, in combination with cisplatin	Compliance with Authority Required procedures - Streamlined Authority Code 3906
	C3913		Where the patient is receiving treatment at/from a Public Hospital Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline	Compliance with Authority Required procedures - Streamlined Authority Code 3913
	C3914		Where the patient is receiving treatment at/from a Public Hospital Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3914
Granisetron	C3050		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration	
Idarubicin	C1006		Acute myelogenous leukaemia	
Ifosfamide	C1325		Relapsed or refractory germ cell tumours following first-line chemotherapy	
	C1327		Relapsed or refractory sarcomas following first-line chemotherapy	
Interferon Alfa-2a	C3180	P3180	Where the patient is receiving treatment at/from a Public Hospital Hairy cell leukaemia	Compliance with Authority Required procedures - Streamlined Authority Code 3180
	C3895	P3895	Where the patient is receiving treatment at/from a Public Hospital Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	Compliance with Authority Required procedures - Streamlined Authority Code 3895
	C3899	P3899	Where the patient is receiving treatment at/from a Public Hospital Myeloproliferative disease with excessive thrombocytosis	Compliance with Authority Required procedures - Streamlined Authority Code 3899
Interferon Alfa-2b	C3180	P3180	Where the patient is receiving treatment at/from a Public Hospital	Compliance with Authority Required

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			Hairy cell leukaemia	procedures - Streamlined Authority Code 3180
	C3895	P3895	Where the patient is receiving treatment at/from a Public Hospital	Compliance with Authority Required procedures - Streamlined Authority Code 3895
			Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	
	C3898	P3898	Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy	Compliance with Authority Required procedures – Streamlined Authority Code 3898
Irinotecan	C3184		Metastatic colorectal cancer in patients with a World Health Organisation performance status of 2 or less	Compliance with Authority Required procedures - Streamlined Authority Code 3184
Mesna	C1618		Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide	
Methotrexate		P3925	Patients receiving treatment with a high dose regimen	
Ondansetron	C3050		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration	
Oxaliplatin	C3900		Metastatic colorectal cancer in a patient with a World Health Organisation performance status of 2 or less, when used in combination with capecitabine	Compliance with Authority Required procedures - Streamlined Authority Code 3900
	C3901		Metastatic colorectal cancer in a patient with a World Health Organisation performance status of 2 or less, when used in combination with fluorouracil and folinic acid	Compliance with Authority Required procedures - Streamlined Authority Code 3901
	C3930		Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with capecitabine	Compliance with Authority Required procedures - Streamlined Authority Code 3930
	C3939		Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with 5-fluorouracil and folinic acid	Compliance with Authority Required procedures - Streamlined Authority Code 3939

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
Paclitaxel	C3186		Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound	Compliance with Authority Required procedures - Streamlined Authority Code 3186
	C3890		Locally advanced or metastatic non-small cell lung cancer	Compliance with Authority Required procedures - Streamlined Authority Code 3890
	C3893		Advanced breast cancer after failure of prior therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3893
	C3902		Primary treatment of ovarian cancer in combination with a platinum compound	Compliance with Authority Required procedures - Streamlined Authority Code 3902
	C3917		Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide	Compliance with Authority Required procedures - Streamlined Authority Code 3917
	C3918		Treatment of HER2 positive early breast cancer in combination with trastuzumab	Compliance with Authority Required procedures - Streamlined Authority Code 3918
Paclitaxel, nanoparticle albumin-bound	C3897		Metastatic breast cancer after failure of prior therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3897
Palonosetron	C3545		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration	
Pemetrexed	C2957		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where the dose per treatment cycle does	Compliance with Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			not exceed 500 mg per metre squared body surface area (BSA) and where the patient's BSA is included in the authority application	
	C2958		Where the patient is receiving treatment in the community setting or at/from a Private Hospital Mesothelioma, in combination with cisplatin, where the dose per treatment cycle does not exceed 500 mg per metre squared body surface area (BSA) and where the patient's BSA is included in the authority application	Compliance with Authority Required procedures
	C3885		Where the patient is receiving treatment at/from a Public Hospital Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where the dose per treatment cycle does not exceed 500 mg per metre squared body surface area (BSA) and where the patient's BSA is documented in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 3885
	C3886		Where the patient is receiving treatment at/from a Public Hospital Mesothelioma, in combination with cisplatin, where the dose per treatment cycle does not exceed 500 mg per metre squared body surface area (BSA) and where the patient's BSA is documented in the patient's medical records at the time the treatment cycle is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 3886
Raltitrexed	C3185		For use as a single agent in the treatment of advanced colorectal cancer	Compliance with Authority Required procedures - Streamlined Authority Code 3185
Rituximab	C1744	P1744	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma	Compliance with Authority Required procedures
	C1745	P1745	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma	Compliance with Authority Required procedures
	C2068	P2068	Where the patient is receiving treatment in the community setting or at/from	Compliance with Authority Required

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			a Private Hospital Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy	procedures
	C2386	P2386	Where the patient is receiving treatment in the community setting or at/from a Private Hospital Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma in combination with chemotherapy	Compliance with Authority Required procedures
	C3908	P3908	Where the patient is receiving treatment at/from a Public Hospital Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma	Compliance with Authority Required procedures - Streamlined Authority Code 3908
	C3909	P3909	Where the patient is receiving treatment at/from a Public Hospital Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma	Compliance with Authority Required procedures - Streamlined Authority Code 3909
	C3912	P3912	Where the patient is receiving treatment at/from a Public Hospital Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy	Compliance with Authority Required procedures - Streamlined Authority Code 3912
	C3915	P3915	Where the patient is receiving treatment at/from a Public Hospital Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma in combination with chemotherapy	Compliance with Authority Required procedures - Streamlined Authority Code 3915
	C3931	P3931	Where the patient is receiving treatment in the community setting or at/from a Private Hospital CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide	Compliance with Authority Required procedures
	C3932	P3932	Where the patient is receiving treatment at/from a Public Hospital CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide	Compliance with Authority Required procedures - Streamlined Authority Code 3932

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
Topotecan	C3186		Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound	Compliance with Authority Required procedures - Streamlined Authority Code 3186
Trastuzumab	C3926	P3926	Initial treatment (3-weekly regimen) Initial treatment for HER2 positive early breast cancer commencing concurrently with adjuvant chemotherapy following surgery. The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes: (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and (ii) a copy of the signed patient acknowledgement form. For a patient on the 3-weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 8 mg per kg	Compliance with modified Written Authority Required procedures
	C3927	P3927	Initial treatment (weekly regimen) Initial treatment for HER2 positive early breast cancer commencing	Compliance with modified Written Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			concurrently with adjuvant chemotherapy following surgery. The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes: (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and (ii) a copy of the signed patient acknowledgement form. For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 4 mg per kg	
	C3928	P3928	Continuing treatment (3-weekly regimen) Continuing treatment for HER2 positive early breast cancer where the patient has previously received treatment with PBS-subsidised trastuzumab. The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Trastuzumab must not be used in patients with a left ventricular ejection	Compliance with Written or Telephone Authority Required procedures

Federal Register of Legislative Instruments F2011L02491

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment. Authority applications for continuing treatment may be made by telephone. For a patient on the 3-weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 6 mg per kg. Breaks in therapy. Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose. Authority applications for new loading doses may be made by telephone	
	C3929	P3929	Continuing treatment (weekly regimen) Continuing treatment for HER2 positive early breast cancer where the patient has previously received treatment with PBS-subsidised trastuzumab. The patient is eligible to receive sufficient trastuzumab to complete 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Trastuzumab must not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment. Authority applications for continuing treatment may be made by telephone. For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 2 mg per kg. Breaks in therapy. Where a patient has a break in trastuzumab therapy of more than 1 week	Compliance with Written or Telephone Authority Required procedures

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements — Part of Circumstances
			but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose. Authority applications for new loading doses may be made by telephone	
Tropisetron	C3050		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration	
Vinorelbine	C3890		Locally advanced or metastatic non-small cell lung cancer	Compliance with Authority Required procedures – Streamlined Authority Code 3890
	C3907		Advanced breast cancer after failure of prior therapy which includes an anthracycline	Compliance with Authority Required procedures – Streamlined Authority Code 3907

Schedule 5 Patient contributions

(sections 54 to 58)

Listed Drug	Form	Manner of Administration	Brand	Quantity or Number of Units	Approved Ex-manufacturer Price	Claimed Ex-manufacturer Price
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	Hospira Pty Ltd	1	$40.89	$77.67

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.