PB 87 of 2011

National Health (Chemotherapy Pharmaceuticals Access Program) Special Arrangement 2011

as amended

made under subsections 100 (1) and (2) of the

National Health Act 1953

This compilation was prepared on 1 March 2012
taking into account amendments up to PB 3 of 2012

Prepared by the Office of Legislative Drafting and Publishing,
Attorney-General's Department, Canberra

Page

Contents

Part 1 Preliminary

Division 1 General

1 Name of Special Arrangement [see Note 1]

(1) This Special Arrangement is the *National Health (Chemotherapy Pharmaceuticals Access Program) Special Arrangement 2011*.

(2) This Special Arrangement may also be cited as PB 87 of 2011.

2 Commencement

This Special Arrangement commences on 1 December 2011.

3 Revocation

Instrument PB 117 of 2010 is revoked.

4 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*.

approved hospital means a public hospital that:

(a) has an approved hospital authority; and

(b) is participating in a Pharmaceutical Reform Arrangement within the meaning of the National Healthcare Agreement.

approved hospital authority, for an approved hospital, means the hospital authority for the hospital that is approved by the Minister under section 94 of the Act.

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

benefit card means any of the following:

(a) a PBS Entitlement Card;

(b) a PBS Safety Net Concession Card;

(c) a Pensioner Concession Card;

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

(e) a Commonwealth Seniors Health Card;

(f) a Cleft Lip and Palate Card;

(g) a DVA Gold Card;

(h) a DVA White Card;

(i) a DVA Orange Card;

(j) War Widow/Widower Transport Card;

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

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

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

dispensed price, for the supply of a chemotherapy pharmaceutical benefit by an approved hospital authority, has the meaning given by section 31.

eligible medical practitioner, for the prescription of a chemotherapy pharmaceutical benefit under this Special Arrangement to an eligible patient, means a medical practitioner who is affiliated with the approved hospital at or from which the eligible patient is receiving treatment.

eligible patient means a person who:

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

(b) is receiving medical treatment by an eligible medical practitioner at, or from, an approved hospital as:

(i) a non-admitted patient; or

(ii) a day admitted patient; or

(iii) a patient on discharge.

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

hospital authority means the governing body of a public hospital.

manufacturers' pack has the same meaning as in the determination made under paragraph 98B(1)(a) of the Act, as in force from time to time.

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

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

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

Streamlined Authority Code means the code mentioned in section 17.

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:

- Chief Executive Medicare
- pharmaceutical benefit
- pharmaceutical item
- public hospital
- Secretary.

Division 2 Chemotherapy pharmaceutical benefits

5 Pharmaceutical benefits covered by this Special Arrangement

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

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

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

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

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

6 Application of Part VII of the Act

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

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

Note See subsection 100 (3) of the Act.

7 Responsible person

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

(2) For subsection (1):

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

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

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

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

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

8 Authorised prescriber

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

(2) For this Special Arrangement:

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

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

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

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

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

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

(5) Subsections 88(1), 88(1A), 88(1C), 88(1D) and 88(1E) of the Act do not apply to the supply of a chemotherapy pharmaceutical benefit under this Special Arrangement.

9 Prescription circumstances

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

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

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

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

Note Circumstances for a code mentioned in the column headed 'Circumstances' in Schedule 1 have been determined by the Minister under paragraph 85 (7) (b) of the Act.

10 Methods of prescribing a chemotherapy pharmaceutical benefit

(1) An eligible medical practitioner may prescribe a chemotherapy pharmaceutical benefit under this Special Arrangement by:

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

(b) preparing a medication chart for the chemotherapy pharmaceutical benefit in accordance with section 11.

(2) A medication chart prepared in accordance with section 11 is taken to be a duly written prescription for regulation 19 of the Regulations.

11 Information to be included in medication chart

For paragraph 10 (1) (b), a medication chart for an eligible patient must include the following information:

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

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

(c) the Streamlined Authority Code for the chemotherapy pharmaceutical benefit, if applicable;

(d) the patient's name and address;

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

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

(g) the name of the chemotherapy pharmaceutical benefit;

(h) the strength of the chemotherapy pharmaceutical benefit;

(i) the quantity or dosage of the chemotherapy pharmaceutical benefit or both the quantity and dosage of the chemotherapy pharmaceutical benefit;

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

(k) the date the medication chart is prepared.

Division 3 Authority required procedures

12 Authority required procedures

(1) This section applies to a chemotherapy pharmaceutical benefit if the circumstances mentioned in Schedule 3 for a circumstances code mentioned in Schedule 1 for the chemotherapy pharmaceutical benefit include any of the following:

(a) Compliance with Authority Required procedures;

(b) Compliance with Written Authority Required procedures;

(c) Compliance with Telephone Authority Required procedures;

(d) Compliance with Written or Telephone Authority Required procedures.

(2) A prescription written in accordance with paragraph 10 (1) (a) for the supply of the chemotherapy pharmaceutical benefit must be:

(a) submitted by the eligible medical practitioner to the Chief Executive Medicare in accordance with section 13; and

(b) authorised by the Chief Executive Medicare in accordance with section 14.

(3) A medication chart prepared in accordance with paragraph 10 (1) (b) for the supply of the chemotherapy pharmaceutical benefit must be:

(a) submitted by a pharmacist employed by the approved hospital authority to the Chief Executive Medicare in accordance with section 15; and

(b) authorised by the Chief Executive Medicare in accordance with section 16.

13 Authority required procedures — submission of paragraph 10 (1) (a) prescription

(1) If subsection 12 (2) applies to a prescription for the supply of a chemotherapy pharmaceutical benefit, the eligible medical practitioner must:

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

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

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

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

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

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

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

(d) 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 a prescription for the supply of the chemotherapy pharmaceutical benefit prepared and signed by the eligible medical practitioner in accordance with subparagraph (a) (i), (ii), (iii) or (iv).

(2) If a circumstance mentioned in Schedule 3 for a circumstances code applying to the chemotherapy pharmaceutical benefit includes Compliance with Written Authority Required procedures, the eligible medical practitioner must submit a prescription for the supply of the chemotherapy pharmaceutical benefit to the Chief Executive Medicare in accordance with paragraph (1) (a).

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

Federal Register of Legislative Instruments F2012C00127

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

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

14 Authority required procedures — authorisation of paragraph 10 (1) (a) prescription

(1) A prescription submitted in accordance with paragraph 13 (1) (a) may be authorised by the Chief Executive Medicare:

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

(b) either:

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

(ii) in any other case:

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

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

(2) A prescription submitted in accordance with paragraph 13 (1) (b) may be authorised by the Chief Executive Medicare telling the eligible medical practitioner by telephone, at the time the Chief Executive Medicare is given details of the prescription, that the prescription is authorised.

(3) A prescription submitted in accordance with paragraph 13 (1) (d) may be authorised by the Chief Executive Medicare sending his or her authorisation by electronic communication, to the eligible medical practitioner.

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

(a) the Chief Executive Medicare must tell the eligible medical practitioner by telephone or by electronic communication the number given by the CEO to the prescription; and

(b) the eligible medical practitioner must:

(i) mark that number on the prescription; and

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

(5) A prescription submitted in accordance with paragraph 13 (1) (c) is taken to have been authorised by the Chief Executive Medicare if the eligible medical practitioner completes the prescription in accordance with the instructions given in the emergency telephone message.

15 Authority required procedures — submission of paragraph 10 (1) (b) medication chart

(1) If subsection 12 (3) applies to a medication chart prepared in accordance with paragraph 10 (1) (b) for the supply of a chemotherapy pharmaceutical benefit, a pharmacist employed by the approved hospital authority must, on behalf of the eligible medical practitioner, submit the information mentioned in section 11 to the Chief Executive Medicare by means of an electronic communication of a kind approved by the Chief Executive Medicare.

(2) If a circumstance mentioned in paragraph (3) (a) or (b) applies, an authorisation for the supply of the chemotherapy pharmaceutical benefit may be obtained if the eligible medical practitioner prepares a prescription in accordance with paragraph 10 (1) (a) and submits that prescription in accordance with section 13 for authorisation under section 14.

(3) For subsection (2), the circumstances are:

(a) the pharmacist attempted to submit the information in accordance with subsection (1) but was unable to do so because the system established by the Chief Executive Medicare for the provision of such authorisation was unavailable; or

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

16 Authority required procedures — authorisation of paragraph 10 (1) (b) medication chart

If the information in the medication chart is submitted in accordance with subsection 15 (1), the supply of the chemotherapy pharmaceutical benefit 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 mentioned in paragraph (a).

17 Streamlined Authority Code

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

(2) The requirements of section 13 are taken to have been complied with, and the Chief Executive Medicare is taken to have authorised the prescription of the chemotherapy pharmaceutical benefit under section 14, if the eligible medical practitioner has:

(a) prepared and signed a prescription for the supply of the chemotherapy pharmaceutical benefit in accordance with subparagraph 13 (a) (i), (ii), (iii) or (iv); and

(b) has written the Streamlined Authority Code on the prescription.

(3) The requirements of section 15 are taken to have been complied with, and the supply of the chemotherapy pharmaceutical benefit is taken to be authorised under section 16, if the eligible medical practitioner has prepared a medication chart in accordance with paragraph 10 (1) (b).

Division 4 Maximum quantity and maximum number of repeats

18 Maximum quantity

(1) This section applies subject to section 19.

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

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

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

(5) For subsection (2), the pharmaceutical item is the listed drug mentioned in Schedule 1:

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

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

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

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

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

19 Variation to maximum quantity or number of units

(1) If an eligible medical practitioner prescribes a supply of a chemotherapy pharmaceutical benefit that is greater than the maximum quantity or number of units permitted under section 18, the supply of a chemotherapy pharmaceutical benefit must be:

(a) if the prescription was written in accordance with paragraph 10 (1) (a) — authorised in accordance with the procedures mentioned in regulation 13 of the Regulations as modified by subsection (2); and

(b) if a medication chart was prepared in accordance with paragraph 10 (1) (b) — authorised in accordance with the procedures mentioned in section 15.

(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 quantity or number of units of the chemotherapy pharmaceutical benefit as described in section 18.

20 Maximum number of repeats — paragraph 10 (1) (a) prescription

(1) If a prescription for the supply of a chemotherapy pharmaceutical benefit is written in accordance with paragraph 10 (1) (a), the maximum number of occasions an eligible medical practitioner may, in 1 prescription, direct that the supply of the chemotherapy pharmaceutical benefit be repeated is the number in the column in Schedule 1 headed 'Number of Repeats' for the chemotherapy pharmaceutical benefit.

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

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

(4) If a prescription is written in accordance with paragraph 10 (1) (a) for the repeat supply of a chemotherapy pharmaceutical benefit that is greater than the maximum number of occasions an eligible medical practitioner may, in 1 prescription, direct the repeat supply of a chemotherapy pharmaceutical benefit under this section, the prescription must be authorised in accordance with the procedures mentioned in regulation 13 of the Regulations as modified by subsection (5).

Federal Register of Legislative Instruments F2012C00127

(5) 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 occasions an eligible medical practitioner may, in one prescription, direct that the supply of the chemotherapy pharmaceutical be repeated as described in this section.

(6) A reference in regulation 24 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 occasions an eligible medical practitioner may, in one prescription, direct that the supply of the chemotherapy pharmaceutical be repeated as described in this section.

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

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

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

21 Maximum number of repeats — paragraph 10 (1) (b) medication chart

(1) If an eligible medical practitioner prescribes a chemotherapy pharmaceutical benefit in a medication chart in accordance with paragraph 10 (1) (b), the eligible medical practitioner may not direct the repeat supply of the chemotherapy pharmaceutical benefit in 1 prescription.

(2) If the medication chart contains a direction that the supply of a chemotherapy pharmaceutical benefit be repeated, the direction is invalid.

Division 5 Section 100 only

22 Section 100 only supply

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

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

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

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

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

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

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

Part 2 Supply of chemotherapy pharmaceutical benefits

23 Entitlement to chemotherapy pharmaceutical benefits

Subject to this Special Arrangement, a person who is an eligible patient is entitled to receive a chemotherapy pharmaceutical benefit under this Special Arrangement without payment or other consideration, other than a charge made under Part 4.

24 Supply of chemotherapy pharmaceutical benefits under this Special Arrangement

This Special Arrangement only applies to the supply of a chemotherapy pharmaceutical benefit to an eligible patient by an approved hospital authority of an approved hospital.

25 Modification to regulations

(1) If the supply of a chemotherapy pharmaceutical benefit is prescribed in accordance with paragraph 10 (1) (b), regulations 22, 26A and 31 and subregulations 25 (2), (3) and (4) of the Regulations do not apply to the supply of the chemotherapy pharmaceutical benefit.

(2) A reference to authority prescription in the Regulations includes a prescription authorised in accordance with Regulation 13 as modified by subsection 19(2) of this Special Arrangement.

26 Acknowledging receipt of supplied chemotherapy pharmaceutical benefits

If the supply of a chemotherapy pharmaceutical benefit is prescribed in accordance with paragraph 10 (1) (b), the eligible medical practitioner or an employee of the approved hospital authority must on the eligible patient's medication chart:

(a) record the date that the chemotherapy pharmaceutical benefit was supplied to the eligible patient; and

(b) sign his or her name.

Part 3 Claims and payment

Division 1 Claims for payment

27 How claims to be made

An approved hospital authority of an approved hospital may make a claim for payment for the supply of the chemotherapy pharmaceutical benefit to an eligible patient under this Special Arrangement in accordance with section 99AAA of the Act, as modified by this Division.

28 Modifications to claim rules

(1) Subject to subsection (2), if an eligible medical practitioner prescribes a chemotherapy pharmaceutical benefit in a medication chart prepared in accordance with paragraph 10 (1) (b), the approved hospital authority must make a claim for the payment of the supply of the chemotherapy pharmaceutical benefit in accordance with section 99AAA and the rules determined by the Minister under subsection 99AAA (8) of the Act.

(2) For a claim mentioned in subsection (1), the requirements in section 99AAA and the rules determined by the Minister under subsection 99AAA (8) of the Act are modified by the following requirements:

(a) the approved hospital authority is not required to supply the medication chart prepared in accordance with paragraph 10 (1) (b) with the claim;

(b) the approved hospital authority must keep an electronic version of the information supplied with the claim in accordance with the rules determined by the Minister under subsection 99AAA(8) for 1 years from the date the chemotherapy pharmaceutical benefit is supplied;

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

(i) the medication chart mentioned in paragraph (a); and

(ii) the information mentioned in paragraph (b).

(3) A reference in the rules determined by the Minister under subsection 99AAA(8) of the Act to an authority prescription is to be read as including a prescription that has been authorised under Regulation 13 as modified by this Special Arrangement.

Division 2 Payments to approved hospital authorities

29 Payments to approved hospital authorities

An approved hospital authority is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of the chemotherapy pharmaceutical benefit is greater than the amount that the approved hospital authority was entitled to charge under Part 4.

30 Method of working out dispensed price

The dispensed price for the supply of a chemotherapy pharmaceutical benefit by an approved hospital authority is to be worked out under Division 3.

Division 3 Dispensed price

31 Dispensed price for supply of a chemotherapy pharmaceutical benefit

Subject to section 33, the ***dispensed price*** for the supply of the chemotherapy pharmaceutical benefit by an approved hospital authority is as follows:

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

(b) if the quantity of the chemotherapy pharmaceutical benefit that is ordered and supplied is less than the quantity contained in the manufacturers' pack — the amount calculated in accordance with section 32.

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

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

(ii) the amount calculated in accordance with section 32 for the quantity supplied that is less than the quantity contained in the manufacturers' pack.

32 Where quantity is less than in manufacturers' pack

If the quantity of a chemotherapy pharmaceutical benefit that is ordered and supplied is less than the quantity contained in the manufacturers' pack (a ***broken quantity***), the amount mentioned in paragraph 31 (b) and subparagraph 31 (c) (ii) is to be calculated by:

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

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

33 Lowest price to be applied

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

ex-manufacturer of the chemotherapy pharmaceutical benefit with the lowest dispensed price.

34 Rounding of dispensed price

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

Part 4 Patient contributions

35 Patient contribution for chemotherapy pharmaceutical benefits mentioned in Schedule 4

(1) This section applies if the chemotherapy pharmaceutical benefit supplied by an approved hospital authority to an eligible patient is:

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

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

(c) administered in a manner mentioned in the column in Schedule 4 headed 'Manner of 'Manner of Administration' for the listed drug mentioned in paragraph (a); and

(d) marketed under the brand mentioned in the column in Schedule 4 headed 'Brand' for the listed drug mentioned in paragraph (a).

(2) The approved hospital authority may charge the eligible patient:

(a) an amount not exceeding the amount that the patient could have been required to pay in accordance with subsection 87(2) of the Act if the patient had obtained the chemotherapy pharmaceutical benefit from an approved pharmacist; and

(b) an amount not exceeding the amount mentioned in subsection 37 (1).

36 Patient contribution for chemotherapy pharmaceutical benefits not mentioned in Schedule 4

(1) This section applies if the chemotherapy pharmaceutical benefit supplied by an approved hospital authority to an eligible patient is not mentioned in Schedule 4.

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

37 Additional patient contributions

(1) For paragraph 35 (2) (b), the amount is the amount calculated by subtracting the amount for the chemotherapy pharmaceutical benefit mentioned in the column in Schedule 4 headed 'Approved Ex-manufacturer Price' from the amount mentioned for the chemotherapy pharmaceutical benefit in the column in Schedule 4 headed 'Claimed Ex-manufacturer Price'.

(2) However, if the quantity of the chemotherapy pharmaceutical benefit being supplied is for more or less than the quantity mentioned in the column in Schedule 4 headed 'Quantity or Number of Units', the amounts mentioned in the columns in Schedule 4 headed 'Approved Ex-manufacturer Price' and 'Claimed Ex-manufacturer Price' must be adjusted proportionally.

Part 5 Transitional arrangements

38 Prescriptions written prior to 1 December 2011

If the supply of a chemotherapy pharmaceutical benefit was prescribed for an eligible patient under the old Arrangements, and the supply was not made prior to the commencement of this Special Arrangement, the supply of the chemotherapy pharmaceutical benefit is taken to have been validly prescribed under this Special Arrangement, and may be supplied to the eligible patient under this Special Arrangement.

39 Old Arrangements

In this Part, ***old Arrangements*** means the *National Health (Chemotherapy Pharmaceuticals Access Program) Special Arrangement 2010* (PB 117 of 2010).

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

(sections 5, 7, 8, 9, 12, 17, 18, 20 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	
Arsenic	Injection concentrate containing arsenic trioxide 10 mg in 10 mL	Injection	Phenasen	PL	EMP	C3891		60	2	D
Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL	Injection	Avastin	RO	EMP	C3894 C3896		1	0	D
	Solution for I.V. infusion 400 mg in 16 mL	Injection	Avastin	RO	EMP	C3894 C3896		1	0	D
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	Hospira Pty Limited	HH	EMP	C1139 C1198		10	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Carboplatin	Solution for I.V. injection 50 mg in 5 mL	Injection	Carboplatin Ebewe	SZ	EMP			2	0	D
			Hospira Pty Limited	HH	EMP			2	0	D
			Pfizer Australia Pty Ltd	PF	EMP			2	0	D
	Solution for I.V. injection 150 mg in 15 mL	Injection	Carboplatin Ebewe	SZ	EMP			6	0	D
			Hospira Pty Limited	HH	EMP			6	0	D
			Pfizer Australia Pty Ltd	PF	EMP			6	0	D
	Solution for I.V. injection 450 mg in 45 mL	Injection	Carboplatin Ebewe	SZ	EMP			2	0	D
			Carboplatin Kabi	PK	EMP			2	0	D
			Hospira Pty Limited	HH	EMP			2	0	D
			Pfizer Australia Pty Ltd	PF	EMP			2	0	D
Cetuximab	Solution for I.V. infusion 100 mg in 20 mL	Injection	Erbitux	SG	EMP	C3903 C3904 C3919 C3920 C3921	P3903 P3904 P3919 P3920	1	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Erbitux	SG	EMP	C3903 C3904 C3919 C3920 C3921	P3921	1	6	D
	Solution for I.V. infusion 500 mg in 100 mL	Injection	Erbitux	SG	EMP	C3903 C3904 C3919 C3920 C3921	P3903 P3904 P3919 P3920	1	0	D
			Erbitux	SG	EMP	C3903 C3904 C3919 C3920 C3921	P3921	1	6	D
Cisplatin	I.V. injection 10 mg in 10 mL	Injection	Pfizer Australia Pty Ltd	PF	EMP			1	0	D
	I.V. injection 50 mg in 50 mL	Injection	Hospira Pty Limited	HH	EMP			1	0	D
			Pfizer Australia Pty Ltd	PF	EMP			1	0	D
	I.V. injection 100 mg in 100 mL	Injection	Cisplatin Ebewe	SZ	EMP			1	0	D
			Hospira Pty Limited	HH	EMP			1	0	D
			Pfizer Australia Pty Ltd	PF	EMP			1	0	D
Cladribine	Injection 10 mg in 5 mL	Injection	Litak	OA	EMP	C3180		7	0	D
	Solution for I.V. infusion 10 mg in 10 mL single use vial	Injection	Leustatin	JC	EMP	C3180		7	0	D
Cyclophosphamide	Powder for injection 500 mg (anhydrous)	Injection	Endoxan	BX	EMP			2	0	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for injection 1 g (anhydrous)	Injection	Endoxan	BX	EMP			1	0	PB
	Powder for injection 2 g (anhydrous)	Injection	Endoxan	BX	EMP			1	0	PB
Cytarabine	Injection 100 mg in 5 mL vial	Injection	Pfizer Australia Pty Ltd	PF	EMP			10	1	D
Docetaxel	Solution concentrate for I.V. infusion 140 mg in 7 mL	Injection	Oncotaxel 140	TA	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956		1	0	D
	Solution concentrate for I.V. infusion 160 mg in 16 mL	Injection	DBL Docetaxel Concentrated Injection	HH	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956		1	0	D
	Powder for I.V. infusion 20 mg with solvent	Injection	Docetaxel SUN	ZF	EMP	C3186 C3884 C3890 C3955		2	0	D
	Powder for I.V. infusion 80 mg with solvent	Injection	Docetaxel SUN	ZF	EMP	C3186 C3884 C3890 C3955		1	0	D
	Solution concentrate for I.V. infusion 20 mg in 1 mL	Injection	Oncotaxel 20	TA	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956	P3888	1	0	D
			Taxotere	SW	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956	P3888	1	0	D
			Oncotaxel 20	TA	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956	P3186 P3884 P3890 P3892 P3916 P3955 P3956	2	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Taxotere	SW	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956	P3186 P3884 P3890 P3892 P3916 P3955 P3956	2	0	D
	Solution concentrate for I.V. infusion 20 mg in 2 mL	Injection	DBL Docetaxel Concentrated Injection	HH	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956	P3888	1	0	D
			Docetaxel Ebewe	HX	EMP	C3186 C3884 C3888 C3890 C3916 C3955	P3888	1	0	D
			Docetaxel Sandoz	SZ	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956	P3888	1	0	D
			DBL Docetaxel Concentrated Injection	HH	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956	P3186 P3884 P3890 P3916 P3955 P3956	2	0	D
			Docetaxel Ebewe	HX	EMP	C3186 C3884 C3888 C3890 C3916 C3955	P3186 P3884 P3890 P3916 P3955	2	0	D
			Docetaxel Sandoz	SZ	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956	P3186 P3884 P3890 P3916 P3955 P3956	2	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	Injection	Taxotere	SW	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956	P3888	1	0	D
			Taxotere	SW	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956	P3186 P3884 P3890 P3892 P3916 P3955 P3956	2	0	D
	Solution concentrate for I.V. infusion 80 mg in 4 mL	Injection	Oncotaxel 80	TA	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956		1	0	D
			Taxotere	SW	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956		1	0	D
	Solution concentrate for I.V. infusion 80 mg in 8 mL	Injection	DBL Docetaxel Concentrated Injection	HH	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956		1	0	D
			Docetaxel Ebewe	HX	EMP	C3186 C3884 C3888 C3890 C3916 C3955		1	0	D
			Docetaxel Sandoz	SZ	EMP	C3186 C3884 C3888 C3890 C3916 C3955 C3956		1	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	Injection	Taxotere	SW	EMP	C3186 C3884 C3888 C3890 C3892 C3916 C3955 C3956		1	0	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	EMP			4	0	D
			Doxorubicin Ebewe	SZ	EMP			4	0	D
			Hospira Pty Limited	HH	EMP			4	0	D
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 20 mg in 10 mL single dose vial	Injection/ intravesical	Adriamycin Solution	PF	EMP			4	0	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	EMP			3	0	D
			Doxorubicin Ebewe	SZ	EMP			3	0	D
			Hospira Pty Limited	HH	EMP			3	0	D
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 100 mg in 50 mL single dose vial	Injection/ intravesical	Doxorubicin Ebewe	SZ	EMP			1	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial	Injection/ intravesical	Adriamycin	PF	EMP			1	0	D
			Doxorubicin Ebewe	SZ	EMP			1	0	D
Doxorubicin - Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	JC	EMP	C3905 C3910 C3911		1	0	D
	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 50 mg in 25 mL	Injection	Caelyx	JC	EMP	C3905 C3910 C3911		1	0	D
Epirubicin	Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL	Injection/intra vesical	Epirubicin Actavis 10	TA	EMP			4	0	D
			Epirubicin Ebewe	SZ	EMP			4	0	D
			Pharmorubicin Solution	PF	EMP			4	0	D
	Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL	Injection/ intravesical	Epirubicin Actavis 20	TA	EMP			4	0	D
			Pharmorubicin Solution	PF	EMP			4	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL	Injection/ intravesical	Epirubicin Actavis 50	TA	EMP			4	0	D
			Epirubicin Ebewe	SZ	EMP			4	0	D
			Hospira Pty Limited	HH	EMP			4	0	D
			Pharmorubicin Solution	PF	EMP			4	0	D
	Solution for injection containing epirubicin hydrochloride 100 mg in 50 mL	Injection/ intravesical	Epirubicin Actavis 100	TA	EMP			2	0	D
			Epirubicin Ebewe	SZ	EMP			2	0	D
			Hospira Pty Limited	HH	EMP			2	0	D
	Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL	Injection/ intravesical	DBL Epirubicin Hydrochloride Injection	HH	EMP			1	0	D
			Epirubicin Actavis 200	TA	EMP			1	0	D
			Epirubicin Ebewe	SZ	EMP			1	0	D
Etoposide	Solution for I.V. infusion 100 mg in 5 mL vial	Injection	Etoposide Ebewe	SZ	EMP			5	0	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Hospira Pty Limited	HH	EMP			5	0	PB
	Powder for I.V. infusion 100 mg (as phosphate)	Injection	Etopophos	BQ	EMP			5	0	PB
	Powder for I.V. infusion 1 g (as phosphate)	Injection	Etopophos	BQ	EMP			1	0	PB
Fludarabine	Powder for I.V. injection containing fludarabine phosphate 50 mg	Injection	Farine	WQ	EMP	C3887		5	3	PB
			Fludara	GZ	EMP	C3887		5	3	PB
			Fludarabine Actavis	TA	EMP	C3887		5	3	PB
	Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL	Injection	Fludarabine Ebewe	SZ	EMP	C3887		5	3	PB
Fluorouracil	Injection 500 mg in 10 mL	Injection	Fluorouracil Ebewe	SZ	EMP			10	0	D
			Hospira Pty Limited	HH	EMP			10	0	D
	Injection 1000 mg in 20mL	Injection	DBL Fluorouracil Injection BP	HH	EMP			5	0	D
			Fluorouracil Ebewe	SZ	EMP			5	0	D
	Injection 2500 mg in 50 mL	Injection	DBL Fluorouracil Injection BP	HH	EMP			2	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Fluorouracil Ebewe	SZ	EMP			2	0	D
	Injection 5000 mg in 100 mL	Injection	Fluorouracil Ebewe	SZ	EMP			1	0	D
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	
			Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	EMP			10	1	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	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	
Fotemustine	Powder for injection 208 mg with solvent	Injection	Muphoran	SE	EMP	C3181		1	4	D
Gemcitabine	Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL	Injection	Gemcitabine Ebewe	SZ	EMP			4	2	D
	Solution for injection 200 mg (as hydrochloride) in 5.3 mL	Injection	DBL Gemcitabine Injection	HH	EMP			4	2	D
	Powder for I.V. infusion 200 mg (as hydrochloride)	Injection	DBL Gemcitabine for Injection	HH	EMP			4	2	D
			Gemcitabine Actavis	TA	EMP			4	2	D
			Gemcitabine Ebewe	SZ	EMP			4	2	D
			Gemcitabine Kabi	PK	EMP			4	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Gemcitabine Sun	ZF	EMP			4	2	D
			Gemcite	ZP	EMP			4	2	D
			Gemplan	WQ	EMP			4	2	D
			Gemzar	LY	EMP			4	2	D
	Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL	Injection	Gemcitabine Ebewe	SZ	EMP			4	2	D
	Solution for injection 1 g (as hydrochloride) in 26.3 mL	Injection	DBL Gemcitabine Injection	HH	EMP			2	2	D
	Solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL	Injection	Gemcitabine Ebewe	SZ	EMP			2	2	D
	Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL	Injection	Gemcitabine Ebewe	SZ	EMP			4	2	D
	Powder for I.V. infusion 1 g (as hydrochloride)	Injection	DBL Gemcitabine for Injection	HH	EMP			2	2	D
			Gemcitabine Actavis	TA	EMP			2	2	D
			Gemcitabine Ebewe	SZ	EMP			2	2	D
			Gemcitabine Kabi	PK	EMP			2	2	D
			Gemcitabine Sun	ZF	EMP			2	2	D
			Gemcite	ZP	EMP			2	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Gemplan	WQ	EMP			2	2	D
			Gemzar	LY	EMP			2	2	D
	Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL	Injection	Gemcitabine Ebewe	SZ	EMP			2	2	D
	Solution for injection 2 g (as hydrochloride) in 52.6 mL	Injection	DBL Gemcitabine Injection	HH	EMP			1	2	D
	Powder for I.V. infusion 2 g (as hydrochloride)	Injection	DBL Gemcitabine for Injection	HH	EMP			1	2	D
			Gemcitabine Kabi	PK	EMP			1	2	D
	Solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL	Injection	Gemcitabine Ebewe	SZ	EMP			1	2	D
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	
Idarubicin	Solution for I.V. injection containing idarubicin hydrochloride 5 mg in 5 mL	Injection	Idarubicin Ebewe	SZ	EMP	C1006		3	0	PB
			Zavedos Solution	PF	EMP	C1006		3	0	PB

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Solution for I.V. injection containing idarubicin hydrochloride 10 mg in 10 mL	Injection	Idarubicin Ebewe	SZ	EMP	C1006		6	0	PB
			Zavedos Solution	PF	EMP	C1006		6	0	PB
Ifosfamide	Powder for I.V. injection 1 g in single dose vial	Injection	Holoxan	BX	EMP	C1325 C1327		5	5	D
	Powder for I.V. injection 2 g in single dose vial	Injection	Holoxan	BX	EMP	C1325 C1327		5	5	D
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	
	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	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	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	
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL	Injection	Camptosar	PF	EMP	C3184		1	3	D
			Hospira Pty Limited	HH	EMP	C3184		1	3	D
			Irinotecan Actavis	TA	EMP	C3184		1	3	D
			Irinotecan Alphapharm	AF	EMP	C3184		1	3	D
			Irinotecan Ebewe	SZ	EMP	C3184		1	3	D
			Irinotecan Kabi	PK	EMP	C3184		1	3	D
			Omegapharm Irinotecan	OE	EMP	C3184		1	3	D
			Tecan	WQ	EMP	C3184		1	3	D
	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Camptosar	PF	EMP	C3184		2	3	D
			Hospira Pty Limited	HH	EMP	C3184		2	3	D
			Irinotecan Actavis	TA	EMP	C3184		2	3	D
			Irinotecan Alphapharm	AF	EMP	C3184		2	3	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Irinotecan Ebewe	SZ	EMP	C3184		2	3	D
			Irinotecan Kabi	PK	EMP	C3184		2	3	D
			Omegapharm Irinotecan	OE	EMP	C3184		2	3	D
			Tecan	WQ	EMP	C3184		2	3	D
	I.V. injection containing irinotecan hydrochloride trihydrate 300 mg in 15 mL	Injection	Camptosar	PF	EMP	C3184		1	3	D
			Irinotecan Ebewe	SZ	EMP	C3184		1	3	D
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Injection	Hospira Pty Limited	HH	EMP	C3184		1	3	D
			Irinotecan Actavis 500	TA	EMP	C3184		1	3	D
			Irinotecan Ebewe	SZ	EMP	C3184		1	3	D
			Tecan	WQ	EMP	C3184		1	3	D
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	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Methotrexate	Injection 5 mg in 2 mL vial	Injection	Hospira Pty Limited	HH	EMP			5	0	
	Injection 50 mg in 2 mL vial	Injection	Hospira Pty Limited	HH	EMP			5	5	
			Pfizer Australia Pty Ltd	PF	EMP			5	5	
	Solution concentrate for I.V. infusion 500 mg in 20 mL vial	Injection	Hospira Pty Limited	HH	EMP			1	0	PB
	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial	Injection	Hospira Pty Limited	HH	EMP			1	0	PB
			Methotrexate Ebewe	SZ	EMP			1	0	PB
	Solution concentrate for I.V. infusion 5000 mg in 50 mL vial	Injection	Methotrexate Ebewe	SZ	EMP			1	0	PB
Mitozantrone	Injection 10 mg (as hydrochloride) in 5 mL	Injection	Pfizer Australia Pty Ltd	PF	EMP			1	0	D
	Injection 20 mg (as hydrochloride) in 10 mL	Injection	Hospira Pty Limited	HH	EMP			1	0	D
			Mitozantrone Ebewe	SZ	EMP			1	0	D
			Onkotrone	BX	EMP			1	0	D
			Pfizer Australia Pty Ltd	PF	EMP			1	0	D
	Injection 25 mg (as hydrochloride) in 12.5 mL	Injection	Onkotrone	BX	EMP			1	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Pfizer Australia Pty Ltd	PF	EMP			1	0	D
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	
	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	

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	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-C laris	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-C laris	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	
Oxaliplatin	Solution concentrate for I.V. infusion 50 mg in 10 mL	Injection	DBL Oxaliplatin Concentrate	HH	EMP	C3900 C3901 C3930 C3939		1	2	D
			Eloxatin	SW	EMP	C3900 C3901 C3930 C3939		1	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Oxaliplatin Kabi	PK	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin SUN	ZF	EMP	C3900 C3901 C3930 C3939		1	2	D
	Powder for I.V. infusion 50 mg	Injection	Hospira Pty Limited	HH	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxalatin	ZP	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Actavis	TA	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Alphapharm	AF	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Ebewe	SZ	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Link	PK	EMP	C3900 C3901 C3930 C3939		1	2	D
			Xalox	WQ	EMP	C3900 C3901 C3930 C3939		1	2	D
	Solution concentrate for I.V. infusion 100 mg in 20 mL	Injection	DBL Oxaliplatin Concentrate	HH	EMP	C3900 C3901 C3930 C3939		1	2	D
			Eloxatin	SW	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Kabi	PK	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin SUN	ZF	EMP	C3900 C3901 C3930 C3939		1	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
	Powder for I.V. infusion 100 mg	Injection	Hospira Pty Limited	HH	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxalatin	ZP	EMP	C3900 C3901 C3030 C3939		1	2	D
			Oxaliplatin Actavis	TA	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Alphapharm	AF	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Ebewe	SZ	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin Link	PK	EMP	C3900 C3901 C3930 C3939		1	2	D
			Winthrop Oxaliplatin	WA	EMP	C3900 C3901 C3930 C3939		1	2	D
			Xalox	WQ	EMP	C3900 C3901 C3930 C3939		1	2	D
	Solution concentrate for I.V. infusion 200 mg in 40 mL	Injection	Eloxatin	SW	EMP	C3900 C3901 C3930 C3939		1	2	D
			Oxaliplatin SUN	ZF	EMP	C3900 C3901 C3930 C3939		1	2	D
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL	Injection	Anzatax	HH	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D
			Paclitaxel Actavis	TA	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Paclitaxel Ebewe	SZ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D
			Paclitaxel Kabi	PK	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D
			Paclitaxel Pfizer	PF	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D
			Plaxel	WQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D
			Taxol	BQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		5	0	D
	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	Injection	Anzatax	HH	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Paclitaxel Actavis	TA	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Paclitaxel Ebewe	SZ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Paclitaxel Kabi	PK	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Paclitaxel Pfizer	PF	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Plaxel	WQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Taxol	BQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
	Solution concentrate for I.V. infusion 150 mg in 25 mL	Injection	Anzatax	HH	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Paclitaxel Actavis	TA	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Paclitaxel Ebewe	SZ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
			Plaxel	WQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		2	0	D
	Solution concentrate for I.V. infusion 300 mg in 50 mL	Injection	Anzatax	HH	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D
			Paclitaxel Actavis	TA	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
			Paclitaxel Ebewe	SZ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D
			Paclitaxel Kabi	PK	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D
			Paclitaxel Pfizer	PF	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D
			Plaxel	WQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D
			Taxol	BQ	EMP	C3186 C3890 C3902 C3917 C3955 C3956		1	0	D
Paclitaxel, nanoparticle albumin-bound	Powder for I.V. injection containing 100 mg paclitaxel	Injection	Abraxane	TS	EMP	C3955 C3956		1	0	D
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Injection	Aloxi	TS	EMP	C3545		1	0	
Pemetrexed	Powder for I.V. infusion 100 mg (as disodium heptahydrate)	Injection	Alimta	LY	EMP	C3885 C3886		1	3	D
	Powder for I.V. infusion 500 mg (as disodium heptahydrate)	Injection	Alimta	LY	EMP	C3885 C3886		1	3	D
Raltitrexed	Powder for I.V. infusion 2 mg in single use vial	Injection	Tomudex	HH	EMP	C3185		3	2	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Mabthera	RO	EMP	C3908 C3909 C3912 C3915 C3932	P3908 P3909	2	3	D
			Mabthera	RO	EMP	C3908 C3909 C3912 C3915 C3932	P3932	2	5	D
			Mabthera	RO	EMP	C3908 C3909 C3912 C3915 C3932	P3912 P3915	2	7	D
	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	RO	EMP	C3908 C3909 C3912 C3915 C3932	P3908 P3909	1	3	D
			Mabthera	RO	EMP	C3908 C3909 C3912 C3915 C3932	P3912 P3915	1	7	D
			Mabthera	RO	EMP	C3908 C3909 C3912 C3915 C3932	P3932	2	5	D
Topotecan	Powder for I.V. infusion 4 mg (as hydrochloride)	Injection	Hycamtin	GK	EMP	C3186		5	1	D
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	
Vinblastine	Solution for I.V. injection containing vinblastine sulfate 10 mg in 10 mL	Injection	Hospira Pty Limited	HH	EMP			5	0	D

Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Purposes	Maximum Quantity	Number of Repeats	Section 100 only
Vincristine	I.V. injection containing vincristine sulfate 1 mg in 1 mL	Injection	Hospira Pty Limited	HH	EMP			10	0	D
			Pfizer Australia Pty Ltd	PF	EMP			10	0	D
Vinorelbine	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	Injection	Hospira Pty Limited	HH	EMP	C3890 C3907		16	2	PB
			Navelbine	FB	EMP	C3890 C3907		16	2	PB
			Vinorelbine Ebewe	SZ	EMP	C3890 C3907		16	2	PB
	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	Injection	Hospira Pty Limited	HH	EMP	C3890 C3907		4	2	PB
			Navelbine	FB	EMP	C3890 C3907		4	2	PB
			Vinorelbine Ebewe	SZ	EMP	C3890 C3907		4	2	PB
			Vinorelbine Kabi	PK	EMP	C3890 C3907		4	2	PB

Schedule 2 Responsible Person Codes

(section 7)

Code	Responsible Person	Australian Business Number
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 Pty Ltd	64 130 119 603
ZP	Spirit Pharmaceuticals Pty Ltd	67 109 225 747

Schedule 3 Circumstances and Purposes Codes

(sections 9, 18 and 20)

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

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; (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	Compliance with Authority Required procedures - Streamlined Authority Code 3621

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
			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	C3891		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	C3894		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, and 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 performance 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		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, and 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	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Cetuximab	C3903	P3903	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	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 – Streamlined Authority Code 3904
	C3919	P3919	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	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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3921	P3921	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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	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 squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil	Compliance with Authority Required procedures – Streamlined Authority 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
	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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3955	P3955	Metastatic breast cancer	Compliance with Authority Required procedures – Streamlined Authority Code 3955
	C3956	P3956	Treatment of HER2 positive breast cancer in combination with trastuzumab	Compliance with Authority Required procedures – Streamlined Authority Code 3956
Doxorubicin - Pegylated Liposomal	C3905		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		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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3911		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 cytometry	Compliance with Authority Required procedures – Streamlined Authority Code 3887
Folinic acid	C1028		Antidote to folic acid antagonists	
Fotemustine	C3181		Metastatic malignant melanoma	Compliance with Authority Required procedures - Streamlined Authority Code 3181

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
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	Hairy cell leukaemia	Compliance with Authority Required procedures – Streamlined Authority Code 3180
	C3895	P3895	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	Myeloproliferative disease with excessive thrombocytosis	Compliance with Authority Required procedures – Streamlined Authority Code 3899

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Interferon Alfa-2b	C3180	P3180	Hairy cell leukaemia	Compliance with Authority Required procedures – Streamlined Authority code 3180
	C3895	P3895	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
	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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
Mesna	C1618		Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide	
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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	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
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
	C3902		Primary treatment of ovarian cancer in combination with a platinum compound	Compliance with Authority Required procedures – Streamlined Authority Code 3902

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3917		Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide	Compliance with Authority Required procedures – Streamlined Authority Code 3917
	C3955		Metastatic breast cancer	Compliance with Authority Required procedures – Streamlined Authority Code 3955
	C3956		Treatment of HER2 positive breast cancer in combination with trastuzumab	Compliance with Authority Required procedures – Streamlined Authority Code 3956
Paclitaxel, nanoparticle albumin-bound	C3955		Metastatic breast cancer	Compliance with Authority Required procedures – Streamlined Authority Code 3955

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3956		Treatment of HER2 positive breast cancer in combination with trastuzumab	Compliance with Authority Required procedures – Streamlined Authority Code 3956
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	C3885		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		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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
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	C3908	P3908	Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma	Compliance with Authority Required procedures – Streamlined Authority Code 3908
	C3909	P3909	Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma	Compliance with Authority Required procedures – Streamlined Authority Code 3909
	C3912	P3912	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

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
	C3915	P3915	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
	C3932	P3932	CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide	Compliance with Authority Required procedures – Streamlined Authority Code 3932
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
Tropisetron	C3050		Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration	

Listed Drug	Circumstances Code	Purposes Code	Circumstances and Purposes	Authority Requirements - Part of Circumstances
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 4 Patient contributions

(sections 35 to 37)

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

Notes to the *National Health (Chemotherapy Pharmaceuticals Access Program) Special Arrangement 2011 (PB 87of 2011)*

Note 1

The *National Health (Chemotherapy Pharmaceuticals Access Program) Special Arrangement 2011 (PB 87 of 2011)* in force under subsections 100 (1) and (2) of the *National Health Act 1953*) as shown in this compilation is amended as indicated in the Tables below.

Table of Instruments

Title	Date of FRLI Registration	Date of commencement	Application, saving or transitional provisions
PB 87 of 2011	30 Nov 2011 (*see* F2011L02507)	1 Dec 2011	
PB 101 of 2011	20 Dec 2011 (*see* F2011L02753)	1 Jan 2012	—
PB 3 of 2012	23 Feb 2012 (*see* F2012L00378)	1 Mar 2012	—

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Schedule 1	
Schedule 1	am. PB 101 of 2011; PB 3 of 2012
Schedule 3	
Schedule 3	am. PB 101 of 2011; PB 3 of 2012