



Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS SUPPLEMENT

This schedule is also available on the internet at

www.pbs.gov.au

**Effective 1 December 2011 –
31 December 2011**

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the National Health Act 1953. However, at the time of distribution the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislative Instruments website at <http://www.frli.gov.au>.

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SUMMARY OF CHANGES

The explanatory notes section of this schedule provides information on the prescribing and dispensing of chemotherapy drugs under the Efficient Funding of Chemotherapy Drugs — Section 100 Arrangements.

In addition to the commencement of these new arrangements, the changes listed below take effect from 1 December 2011.

Additions

Addition – Restrictions

7234R, 4394G	Fluorouracil	Injection	Injection 500 mg in 10 mL Injection 1000 mg in 20 mL Injection 2500 mg in 50 mL Injection 5000 mg in 100 mL
7239B, 4431F	Fluorouracil	Injection	Injection 500 mg in 10 mL Injection 1000 mg in 20 mL Injection 2500 mg in 50 mL Injection 5000 mg in 100 mL
7251P, 4512L	Methotrexate	Injection	Injection 5 mg in 2 mL Injection 50 mg in 2 mL Solution concentrate for I.V. infusion 500 mg in 20 mL Solution concentrate for I.V. infusion 1000 mg in 10 mL Solution concentrate for I.V. infusion 5000 mg in 50 mL
7259C, 4615X	Rituximab	Injection	Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL

Addition – Caution

The following caution has been applied to all **Docetaxel** items:

CAUTION

Pharmaceutical benefits containing docetaxel may have different concentrations.

Deletions

Deletion – Item

Thiotepa, Powder for injection 15 mg (Aspen Pharma Pty Ltd)

Alterations

Alteration – Restrictions

7253R, 4542C	Oxaliplatin	Injection	Solution concentrate for I.V. infusion 50 mg in 10 mL Solution concentrate for I.V. infusion 100 mg in 20 mL Solution concentrate for I.V. infusion 200 mg in 40 mL Powder for I.V. infusion 50 mg Powder for I.V. infusion 100 mg
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EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS

Explanatory Notes

In addition to the drugs and medicinal preparations listed in the Schedule of Pharmaceutical Benefits, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements. These alternative arrangements are provided for under section 100 of the *National Health Act 1953*.

Section 100 cancer chemotherapy drugs

New prescribing and dispensing arrangements for certain chemotherapy drugs subsidised by the Pharmaceutical Benefits Scheme (PBS) will take effect from 1 December 2011 under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs initiative (Revised Arrangements).

Chemotherapy drugs used for the treatment of cancer and administered through infusion or injection are covered by these Revised Arrangements. From 1 December 2011 the Revised Arrangements will operate under a new section 100 program which will include certain intravenous chemotherapy drugs, as listed in this Schedule, which were previously supplied through:

- the General Pharmaceutical Benefits Schedule (section 2)
- the Special Authority Program (trastuzumab - Herceptin®), and
- the current Chemotherapy Pharmaceutical Access Program (CPAP).

The Revised Arrangements will apply for both public hospitals and private hospitals/clinics. While private hospitals/clinics will move to the Revised Arrangements from 1 December 2011, the implementation in public hospitals will be phased in until 31 March 2012.

- Where public hospitals have moved to the Revised Arrangements, they will need to comply with the new guidelines for writing prescriptions as set out below.
- Where public hospitals have NOT moved to the Revised Arrangements they can continue to use the existing CPAP S100 arrangements, for supply within the hospital, that currently apply for chemotherapy infusibles (please refer to the CPAP schedule for details).
- Where public hospital prescribers write prescriptions for chemotherapy infusibles, that are to be dispensed outside public hospitals, they will need to comply with the new guidelines for writing prescriptions as set out below.

This Schedule is split into two parts:

Chemotherapy items for public hospital use

Chemotherapy items for private hospital/private clinic use

Prescribing and Supplying - Information for PBS Prescribers and Pharmacists

Drugs are listed based on the relevant unit of measure. Prescribers of chemotherapy drugs must write dose specific prescriptions, which specify the amount of active ingredient/s required for a single infusion or injection using milligrams or other relevant units of measure.

- Prescribing will exclude reference to forms and strengths
- Loading and maintenance doses will need to be prescribed separately
- Prescriptions will no longer take the form of an order for a certain number of items, but will instead order an amount of a drug or drugs at the generic (drug) level
- Prescribers retain the right to prescribe by brand.

This Schedule has been updated to include:

- one item code per drug (in most circumstances) under which brands, forms and strengths are listed
- maximum amount (which replaces maximum quantity) refers to the upper limit in milligrams or other relevant unit of measure

Dispensing software has been upgraded to include an algorithm which will calculate the most cost-efficient combination of vial sizes that make up the required patient dose (one prescription) and calculate the level of remuneration paid.

The algorithm does not determine how the infusion is prepared, however remuneration will be made based on the most cost-efficient combination of vial sizes. Pharmacists will still be able to dispense any subsidised brand or combination of brands.

A dose variation will be allowed by up to 10 percent from the original amount prescribed without requirement for a new prescription on the recommendation of the prescriber.

Same day prescribing will be allowed. Regulations 24 (immediate supply necessary) and 25 (hardship provisions) will not apply for items under this initiative.

To recognise the specialist nature of dispensing chemotherapy drugs the Government has determined new remuneration arrangements. The fee structure for community pharmacies, public hospitals and private hospitals is provided below.

For more information on prescribing and supplying chemotherapy medicines subject to the Revised Arrangements, refer to the PBS website at www.pbs.gov.au.

Authorisation requirements

Authorisation requirements have not been varied by the Revised Arrangements. Items that require an Authority continue to require an Authority from Medicare.

Prior approval is not needed for Authority Required (STREAMLINED) items (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code. Under the Revised Arrangements more items are available as Authority Required (STREAMLINED).

For more information on authorisation requirements, refer to the Explanatory Notes of the Schedule of Pharmaceutical Benefits at www.pbs.gov.au or the Medicare Australia website at www.medicareaustralia.gov.au.

Brand equivalence

An 'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

For other brands of an item, i.e., those not indicated as above, it is unknown whether or not they are equivalent. There may be several reasons for this, such as bioequivalence data not being considered necessary when the products were approved for marketing, or that advice or data have not been forthcoming from sponsors. This does not necessarily suggest a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.

Remuneration arrangements

Fees payable per item claimed:

Section 90 Community Pharmacy (incl. section 92 approved practitioners)

- Ready Prepared Dispensing Fee (\$6.42)
- Preparation fee (\$40) (replaces wholesale fee)
- Distribution fee (\$24)
- Diluent fee (\$4.75)

Section 94 Approved Public Hospital Authority

- Preparation fee (\$40)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee (\$6.42)
- Preparation fee (\$40)
- Distribution fee (\$24) (replaces wholesale fee) (not payable where the drug is trastuzumab)
- Diluent fee (\$4.75)

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**CHEMOTHERAPY ITEMS
FOR PRIVATE HOSPITAL/PRIVATE CLINIC USE**

Special Pharmaceutical Benefits for Private Hospital/Private Clinic use

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 28, in the Schedule of Pharmaceutical Benefits.

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Proposed Dispensed Price for Max. Amount	Total Dispensed Price for Max. Amount	Maximum Recordable Value for Safety Net	Brand, Form, Strength and Manufacturer
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Antineoplastic and immunomodulating agents

Antineoplastic agents

Cytotoxic antibiotics and related substances

Other cytotoxic antibiotics

BLEOMYCIN SULFATE

Restricted Benefit

Germ cell neoplasms.

Restricted Benefit

Lymphoma.

7244G	Injection	30000 i.u.	11	\$80.92	165.13	246.05	34.20	Hospira Pty Limited (Powder for injection 15,000 i.u.)	HH
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Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
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Antineoplastic and immunomodulating agents

Antineoplastic agents

Alkylating agents

Nitrogen mustard analogues

CYCLOPHOSPHAMIDE

7226H	Injection	2800 mg	17	-	145.16	34.20	Endoxan (Powder for injection 1 g)	BX
							Endoxan (Powder for injection 2 g)	BX
							Endoxan (Powder for injection 500 mg)	BX

IFOSFAMIDE

Restricted Benefit

Relapsed or refractory germ cell tumours following first-line chemotherapy.

Restricted Benefit

Relapsed or refractory sarcomas following first-line chemotherapy.

7248L	Injection	4000 mg	19	-	329.77	34.20	Holoxan (Powder for I.V. injection 1 g)	BX
							Holoxan (Powder for I.V. injection 2 g)	BX

Nitrosoureas

FOTEMUSTINE

Authority Required (STREAMLINED)

3181

Metastatic malignant melanoma.

7245H	Injection	220 mg	8	-	2313.83	34.20	Muphoran (Powder for injection 208 mg with solvent)	SE
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Antimetabolites

Folic acid analogues

METHOTREXATE

7250N	Injection	250 mg	5	-	102.27	34.20	Hospira Pty Limited (Injection 5 mg in 2 mL)	HH
							Hospira Pty Limited (Solution concentrate for I.V. infusion 500 mg in 20 mL)	HH
							Methotrexate Ebewe (Solution concentrate for I.V. infusion 5000 mg in 50 mL)	SZ
							^a Hospira Pty Limited (Injection 50 mg in 2 mL)	HH
							^a Hospira Pty Limited (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	HH
							^a Methotrexate Ebewe (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	SZ
							^a Pfizer Australia Pty Ltd (Injection 50 mg in 2 mL)	PF

METHOTREXATE

Restricted Benefit

Patients receiving treatment with a high dose regimen.

7251P	Injection	20000 mg	0	-	2031.17	34.20	Hospira Pty Limited (Injection 5 mg in 2 mL)	HH
							Hospira Pty Limited (Solution concentrate for I.V. infusion 500 mg in 20 mL)	HH
							Methotrexate Ebewe (Solution concentrate for I.V. infusion 5000 mg in 50 mL)	SZ
							^a Hospira Pty Limited (Injection 50 mg in 2 mL)	HH
							^a Hospira Pty Limited (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	HH
							^a Methotrexate Ebewe (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	SZ
							^a Pfizer Australia Pty Ltd (Injection 50 mg in 2 mL)	PF

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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PEMETREXED DISODIUM

Authority Required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.

Authority Required

Mesothelioma in combination with cisplatin.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.

Note

No applications for increased maximum quantities for the 500 mg vial will be authorised.

7255W	Injection	1100 mg	5	-	3576.80	34.20	Alimta (Powder for I.V. infusion 100 mg (base)) Alimta (Powder for I.V. infusion 500 mg (base))	LY LY
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RALTITREXED

Authority Required (STREAMLINED)

3185

For use as a single agent in the treatment of advanced colorectal cancer.

7256X	Injection	7 mg	8	-	1129.05	34.20	Tomudex (Powder for I.V. infusion 2 mg)	HH
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Purine analogues

CLADRIBINE

Authority Required (STREAMLINED)

3180

Hairy cell leukaemia.

7225G	Injection	17 mg	6	-	1407.33	34.20	Leustatin (Solution for I.V. infusion 10 mg in 10 mL) Litak (Injection 10 mg in 5 mL)	JC OA
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FLUDARABINE PHOSPHATE

Authority Required (STREAMLINED)

3887

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.

Stage A progressive disease is defined by at least one 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.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:

- (a) a lymphocytosis, with more than 5000 million lymphocytes per L in the peripheral blood; and
- (b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.

Note

Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical benefits that have the form fludarabine phosphate solution for I.V. injection 50 mg are equivalent for the purposes of substitution.

7233Q	Injection	55 mg	29	-	645.59	34.20	^a Farine (Powder for I.V. injection 50 mg) ^a Fludara (Powder for I.V. injection 50 mg) ^a Fludarabine Actavis (Powder for I.V. injection 50 mg) ^a Fludarabine Ebewe (Solution for I.V. injection 50 mg in 2 mL)	WQ GZ TA SZ
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Pyrimidine analogues

CYTARABINE

7227J	Injection	7000 mg	15	-	809.47	34.20	Pfizer Australia Pty Ltd (Injection 100 mg in 5 mL)	PF
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Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
FLUOROURACIL								
<u>Restricted Benefit</u>								
For patients requiring administration of fluorouracil by intravenous infusion.								
7234R	Injection	5500 mg	11	-	117.33	34.20	Fluorouracil Ebewe (Injection 5000 mg in 100 mL)	SZ
							^a DBL Fluorouracil Injection BP (Injection 1000 mg in 20 mL)	HH
							^a DBL Fluorouracil Injection BP (Injection 2500 mg in 50 mL)	HH
							^a Fluorouracil Ebewe (Injection 1000 mg in 20 mL)	SZ
							^a Fluorouracil Ebewe (Injection 2500 mg in 50 mL)	SZ
							^a Fluorouracil Ebewe (Injection 500 mg in 10 mL)	SZ
							^a Hospira Pty Limited (Injection 500 mg in 10 mL)	HH
FLUOROURACIL								
<u>Restricted Benefit</u>								
For patients requiring administration of fluorouracil by intravenous injection.								
7239B	Injection	1000 mg	23	-	83.15	34.20	Fluorouracil Ebewe (Injection 5000 mg in 100 mL)	SZ
							^a DBL Fluorouracil Injection BP (Injection 1000 mg in 20 mL)	HH
							^a DBL Fluorouracil Injection BP (Injection 2500 mg in 50 mL)	HH
							^a Fluorouracil Ebewe (Injection 1000 mg in 20 mL)	SZ
							^a Fluorouracil Ebewe (Injection 2500 mg in 50 mL)	SZ
							^a Fluorouracil Ebewe (Injection 500 mg in 10 mL)	SZ
							^a Hospira Pty Limited (Injection 500 mg in 10 mL)	HH
GEMCITABINE								
<u>Authority Required</u>								
Locally advanced or metastatic adenocarcinoma of the pancreas.								
<u>Authority Required</u>								
Locally advanced or metastatic non-small cell lung cancer.								
<u>Authority Required</u>								
Locally advanced or metastatic bladder cancer, in combination with cisplatin.								
<u>Authority Required</u>								
Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline.								
<u>Authority Required</u>								
Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy.								
<u>Note</u>								
Pharmaceutical benefits that have the form gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) are equivalent for the purposes of substitution.								
<u>Note</u>								
Pharmaceutical benefits that have the form gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) are equivalent for the purposes of substitution.								
7246J	Injection	3000 mg	17	-	486.77	34.20	Gemcitabine Ebewe (Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL)	SZ
							^a DBL Gemcitabine for Injection (Powder for I.V. infusion 1 g (as hydrochloride))	HH
							^a DBL Gemcitabine for Injection (Powder for I.V. infusion 2 g (as hydrochloride))	HH
							^a DBL Gemcitabine for Injection (Powder for I.V. infusion 200 mg (as hydrochloride))	HH
							^a Gemcitabine Actavis (Powder for I.V. infusion 1 g (as hydrochloride))	TA
							^a Gemcitabine Actavis (Powder for I.V. infusion 200 mg (as hydrochloride))	TA
							^a Gemcitabine Ebewe (Powder for I.V. infusion 1 g (as hydrochloride))	SZ

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a Gemcitabine Ebewe (Powder for I.V. infusion 200 mg (as hydrochloride))	SZ
							^a Gemcitabine Ebewe (Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL)	SZ
							^a Gemcitabine Ebewe (Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL)	SZ
							^a Gemcitabine Kabi (Powder for I.V. infusion 1 g (as hydrochloride))	PK
							^a Gemcitabine Kabi (Powder for I.V. infusion 2 g (as hydrochloride))	PK
							^a Gemcitabine Kabi (Powder for I.V. infusion 200 mg (as hydrochloride))	PK
							^a Gemcitabine Sun (Powder for I.V. infusion 1 g (as hydrochloride))	ZF
							^a Gemcitabine Sun (Powder for I.V. infusion 200 mg (as hydrochloride))	ZF
							^a Gemcite (Powder for I.V. infusion 1 g (as hydrochloride))	ZP
							^a Gemcite (Powder for I.V. infusion 200 mg (as hydrochloride))	ZP
							^a Gemplan (Powder for I.V. infusion 1 g (as hydrochloride))	WQ
							^a Gemplan (Powder for I.V. infusion 200 mg (as hydrochloride))	WQ
							^a Gemzar (Powder for I.V. infusion 1 g (as hydrochloride))	LY
							^a Gemzar (Powder for I.V. infusion 200 mg (as hydrochloride))	LY

Plant alkaloids and other natural products

Vinca alkaloids and analogues

VINBLASTINE SULFATE

7261E	Injection	20 mg	17	-	135.93	34.20	Hospira Pty Limited (Solution for I.V. injection 10 mg in 10 mL)	HH
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VINCRISTINE SULFATE

7262F	Injection	2 mg	7	-	103.53	34.20	^a Hospira Pty Limited (I.V. injection 1 mg in 1 mL)	HH
							^a Pfizer Australia Pty Ltd (I.V. injection 1 mg in 1 mL)	PF

VINORELBINE

Authority Required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority Required (STREAMLINED)

3907

Advanced breast cancer after failure of prior therapy which includes an anthracycline.

7263G	Injection	70 mg	7	-	475.57	34.20	^a Hospira Pty Limited (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	HH
							^a Hospira Pty Limited (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	HH
							^a Navelbine (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	FB
							^a Navelbine (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	FB
							^a Vinorelbine Ebewe (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	SZ
							^a Vinorelbine Ebewe (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	SZ
							^a Vinorelbine Kabi (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	PK

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Podophyllotoxin derivatives

ETOPOSIDE							
7237X	Injection	440 mg	14	-	221.27	34.20	Etopophos (Powder for I.V. infusion 1 g (as phosphate)) BQ Etopophos (Powder for I.V. infusion 100 mg (as phosphate)) BQ ^a Etoposide Ebewe (Solution for I.V. infusion 100 mg in 5 mL) SZ ^a Hospira Pty Limited (Solution for I.V. infusion 100 mg in 5 mL) HH

Taxanes

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3916

Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

7281F	Injection	250 mg	5	-	3883.76	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) HH Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) TA ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) HH ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL) HH ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL) HX ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL) HX ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL) SZ ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL) SZ ^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL) TA ^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL) TA ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent) SW ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent) SW ^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL) SW ^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL) SW
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DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3918

Treatment of HER2 positive early breast cancer in combination with trastuzumab.

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	
Note							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.							
Note							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.							
7282G	Injection	250 mg	5	-	3883.76	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) HH Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) TA ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) HH ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL) HH ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL) SZ ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL) SZ ^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL) TA ^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL) TA ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent) SW ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent) SW ^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL) SW ^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL) SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3888

Neoadjuvant treatment of a patient with a WHO 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.

Note

The carcinoma can be considered inoperable for technical or organ preservation reasons.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

7283H	Injection	250 mg	5	-	3883.76	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) HH Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) TA ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) HH ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL) HH ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL) HX ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL) HX ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL) SZ ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL) SZ
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Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3892

Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.

Note

A maximum of four cycles of treatment will be authorised under this restriction.

Note

Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

7284J	Injection	250 mg	5	-	3883.76	34.20	Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL)	TA
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority Required (STREAMLINED)

3186

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.

Authority Required (STREAMLINED)

3884

Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.

Note

A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
Authority Required (STREAMLINED)								
3893								
Advanced breast cancer after failure of prior therapy.								
Note								
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and 20 mg in 2 mL, docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) and docetaxel powder for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.								
Note								
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and 80 mg in 8 mL, docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) and docetaxel powder for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.								
7285K	Injection	250 mg	5	-	3883.76	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL) ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL) ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL) ^a Docetaxel SUN (Powder for I.V. infusion 20 mg with solvent) ^a Docetaxel SUN (Powder for I.V. infusion 80 mg with solvent) ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL) ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL) ^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL) ^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL) ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent) ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent) ^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL) ^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	HH TA HH HH HX HX ZF ZF SZ SZ TA TA SW SW SW SW

NAB PACLITAXEL

Authority Required (STREAMLINED)

3897

Metastatic breast cancer after failure of prior therapy.

7270P	Injection	580 mg	5	-	2554.07	34.20	Abraxane (Powder for I.V. injection 100 mg (base))	TS
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PACLITAXEL

Authority Required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority Required (STREAMLINED)

3902

Primary treatment of ovarian cancer in combination with a platinum compound.

Authority Required (STREAMLINED)

3186

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.

Authority Required (STREAMLINED)

3917

Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide.

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$		Brand, Form, Strength and Manufacturer	
Authority Required (STREAMLINED)									
3918									
Treatment of HER2 positive early breast cancer in combination with trastuzumab.									
Authority Required (STREAMLINED)									
3893									
Advanced breast cancer after failure of prior therapy.									
7254T	Injection	450 mg	3	-	1259.27	34.20	a	Anzatax (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)	HH
							a	Anzatax (Solution concentrate for I.V. infusion 150 mg in 25 mL)	HH
							a	Anzatax (Solution concentrate for I.V. infusion 30 mg in 5 mL)	HH
							a	Anzatax (Solution concentrate for I.V. infusion 300 mg in 50 mL)	HH
							a	Paclitaxel Actavis (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)	TA
							a	Paclitaxel Actavis (Solution concentrate for I.V. infusion 150 mg in 25 mL)	TA
							a	Paclitaxel Actavis (Solution concentrate for I.V. infusion 30 mg in 5 mL)	TA
							a	Paclitaxel Actavis (Solution concentrate for I.V. infusion 300 mg in 50 mL)	TA
							a	Paclitaxel Ebewe (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)	SZ
							a	Paclitaxel Ebewe (Solution concentrate for I.V. infusion 150 mg in 25 mL)	SZ
							a	Paclitaxel Ebewe (Solution concentrate for I.V. infusion 30 mg in 5 mL)	SZ
							a	Paclitaxel Ebewe (Solution concentrate for I.V. infusion 300 mg in 50 mL)	SZ
							a	Paclitaxel Kabi (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)	PK
							a	Paclitaxel Kabi (Solution concentrate for I.V. infusion 30 mg in 5 mL)	PK
							a	Paclitaxel Kabi (Solution concentrate for I.V. infusion 300 mg in 50 mL)	PK
							a	Plaxel (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)	WQ
							a	Plaxel (Solution concentrate for I.V. infusion 150 mg in 25 mL)	WQ
							a	Plaxel (Solution concentrate for I.V. infusion 30 mg in 5 mL)	WQ
							a	Plaxel (Solution concentrate for I.V. infusion 300 mg in 50 mL)	WQ
							a	Taxol (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)	BQ
							a	Taxol (Solution concentrate for I.V. infusion 30 mg in 5 mL)	BQ
							a	Taxol (Solution concentrate for I.V. infusion 300 mg in 50 mL)	BQ

Cytotoxic antibiotics and related substances Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE

7229L	Injection/intravesical	135 mg	11	-	166.18	34.20		Adriamycin Solution (Solution for I.V. injection or intravesical administration 20 mg in 10 mL)	PF
								Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 100 mg in 50 mL)	SZ
							a	Adriamycin (Solution for I.V. injection or intravesical administration 200 mg in 100 mL)	PF
							a	Adriamycin Solution (Solution for I.V. injection or intravesical administration 10 mg in 5 mL)	PF
							a	Adriamycin Solution (Solution for I.V. injection or intravesical administration 50 mg in 25 mL)	PF
							a	Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 10 mg in 5 mL)	SZ
							a	Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 200 mg in 100 mL)	SZ

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 50 mg in 25 mL)	SZ
							^a Hospira Pty Limited (Solution for I.V. injection or intravesical administration 10 mg in 5 mL)	HH
							^a Hospira Pty Limited (Solution for I.V. injection or intravesical administration 50 mg in 25 mL)	HH
DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL								
<u>Authority Required</u>								
Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.								
<u>Authority Required</u>								
Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane.								
<u>Authority Required</u>								
Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.								
7230M	Injection	100 mg	5	-	3111.77	34.20	Caelyx (Suspension for I.V. infusion 20 mg in 10 mL)	JC
							Caelyx (Suspension for I.V. infusion 50 mg in 25 mL)	JC
EPIRUBICIN HYDROCHLORIDE								
7231N	Injection/intravesical	220 mg	5	-	840.16	34.20	Pharmorubicin Solution (Solution for injection 20 mg in 10 mL)	PF
							^a DBL Epirubicin Hydrochloride Injection (Solution for injection 200 mg in 100 mL)	HH
							^a Epirubicin Ebewe (Solution for injection 10 mg in 5 mL)	SZ
							^a Epirubicin Ebewe (Solution for injection 100 mg in 50 mL)	SZ
							^a Epirubicin Ebewe (Solution for injection 200 mg in 100 mL)	SZ
							^a Epirubicin Ebewe (Solution for injection 50 mg in 25 mL)	SZ
							^a Hospira Pty Limited (Solution for injection 100 mg in 50 mL)	HH
							^a Hospira Pty Limited (Solution for injection 50 mg in 25 mL)	HH
							^a Pharmorubicin Solution (Solution for injection 10 mg in 5 mL)	PF
							^a Pharmorubicin Solution (Solution for injection 50 mg in 25 mL)	PF
IDARUBICIN HYDROCHLORIDE								
<u>Restricted Benefit</u>								
Acute myelogenous leukaemia.								
7247K	Injection	30 mg	5	-	924.77	34.20	^a Idarubicin Ebewe (Solution for I.V. injection 10 mg in 10 mL)	SZ
							^a Idarubicin Ebewe (Solution for I.V. injection 5 mg in 5 mL)	SZ
							^a Zavedos Solution (Solution for I.V. injection 10 mg in 10 mL)	PF
							^a Zavedos Solution (Solution for I.V. injection 5 mg in 5 mL)	PF
MITOZANTRONE HYDROCHLORIDE								
7252Q	Injection	30 mg	5	-	288.92	34.20	Pfizer Australia Pty Ltd (Injection 10 mg (base) in 5 mL)	PF
							^a Hospira Pty Limited (Injection 20 mg (base) in 10 mL)	HH
							^a Mitozantrone Ebewe (Injection 20 mg (base) in 10 mL)	SZ
							^a Onkotrone (Injection 20 mg (base) in 10 mL)	BX
							^a Onkotrone (Injection 25 mg (base) in 12.5 mL)	BX
							^a Pfizer Australia Pty Ltd (Injection 20 mg (base) in 10 mL)	PF
							^a Pfizer Australia Pty Ltd (Injection 25 mg (base) in 12.5 mL)	PF

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Other antineoplastic agents

Platinum compounds

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
CARBOPLATIN							
7222D	Injection	900 mg	5	-	317.23	34.20	^a Carboplatin Ebewe (Solution for I.V. injection 150 mg in 15 mL) SZ ^a Carboplatin Ebewe (Solution for I.V. injection 450 mg in 45 mL) SZ ^a Carboplatin Ebewe (Solution for I.V. injection 50 mg in 5 mL) SZ ^a Hospira Pty Limited (Solution for I.V. injection 150 mg in 15 mL) HH ^a Hospira Pty Limited (Solution for I.V. injection 450 mg in 45 mL) HH ^a Hospira Pty Limited (Solution for I.V. injection 50 mg in 5 mL) HH ^a Pfizer Australia Pty Ltd (Solution for I.V. injection 150 mg in 15 mL) PF ^a Pfizer Australia Pty Ltd (Solution for I.V. injection 450 mg in 45 mL) PF ^a Pfizer Australia Pty Ltd (Solution for I.V. injection 50 mg in 5 mL) PF

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
CISPLATIN							
7224F	Injection	220 mg	14	-	131.07	34.20	Pfizer Australia Pty Ltd (I.V. injection 10 mg in 10 mL) PF ^a Cisplatin Ebewe (I.V. injection 100 mg in 100 mL) SZ ^a Hospira Pty Limited (I.V. injection 100 mg in 100 mL) HH ^a Hospira Pty Limited (I.V. injection 50 mg in 50 mL) HH ^a Pfizer Australia Pty Ltd (I.V. injection 100 mg in 100 mL) PF ^a Pfizer Australia Pty Ltd (I.V. injection 50 mg in 50 mL) PF

OXALIPLATIN

Authority Required (STREAMLINED)

3930

Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with capecitabine.

Authority Required (STREAMLINED)

3939

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.

Authority Required (STREAMLINED)

3900

Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with capecitabine.

Authority Required (STREAMLINED)

3901

Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with 5-fluorouracil and folinic acid.

Note

Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer. Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

Note

Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 50 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 50 mg are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 100 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 100 mg are equivalent for the purposes of substitution.

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
7253R	Injection	300 mg	11	-	585.85	34.20	^a DBL Oxaliplatin Concentrate (Solution concentrate for I.V. infusion 100 mg in 20 mL) HH ^a DBL Oxaliplatin Concentrate (Solution concentrate for I.V. infusion 50 mg in 10 mL) HH ^a Eloxatin (Solution concentrate for I.V. infusion 100 mg in 20 mL) SW ^a Eloxatin (Solution concentrate for I.V. infusion 200 mg in 40 mL) SW

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
							^a Eloxatin (Solution concentrate for I.V. infusion 50 mg in 10 mL) SW
							^a Hospira Pty Limited (Powder for I.V. infusion 100 mg) HH
							^a Hospira Pty Limited (Powder for I.V. infusion 50 mg) HH
							^a Oxalatin (Powder for I.V. infusion 100 mg) ZP
							^a Oxalatin (Powder for I.V. infusion 50 mg) ZP
							^a Oxaliplatin Actavis (Powder for I.V. infusion 100 mg) TA
							^a Oxaliplatin Actavis (Powder for I.V. infusion 50 mg) TA
							^a Oxaliplatin Alphapharm (Powder for I.V. infusion 100 mg) AF
							^a Oxaliplatin Alphapharm (Powder for I.V. infusion 50 mg) AF
							^a Oxaliplatin Ebewe (Powder for I.V. infusion 100 mg) SZ
							^a Oxaliplatin Ebewe (Powder for I.V. infusion 50 mg) SZ
							^a Oxaliplatin Kabi (Solution concentrate for I.V. infusion 100 mg in 20 mL) PK
							^a Oxaliplatin Kabi (Solution concentrate for I.V. infusion 50 mg in 10 mL) PK
							^a Oxaliplatin Link (Powder for I.V. infusion 100 mg) PK
							^a Oxaliplatin Link (Powder for I.V. infusion 50 mg) PK
							^a Oxaliplatin SUN (Solution concentrate for I.V. infusion 100 mg in 20 mL) ZF
							^a Oxaliplatin SUN (Solution concentrate for I.V. infusion 200 mg in 40 mL) ZF
							^a Oxaliplatin SUN (Solution concentrate for I.V. infusion 50 mg in 10 mL) ZF
							^a Winthrop Oxaliplatin (Powder for I.V. infusion 100 mg) WA
							^a Xalox (Powder for I.V. infusion 100 mg) WQ
							^a Xalox (Powder for I.V. infusion 50 mg) WQ

Monoclonal antibodies

BEVACIZUMAB

Authority Required

Initial PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with previously untreated metastatic colorectal cancer with a WHO performance status of 0 or 1.

Doses greater than 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks will not be PBS-subsidised. The patient's WHO performance status and body weight must be recorded in the patient's medical records at the time the treatment cycle is initiated.

Note

Not for use as monotherapy.

Authority Required

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.

Doses greater than 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks will not be PBS-subsidised. The patient's body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Note

Not for use as monotherapy.

Note

Special Pricing Arrangements apply.

7243F	Injection	900 mg	11	-	4042.11	34.20	Avastin (Solution for I.V. infusion 100 mg in 4 mL) RO Avastin (Solution for I.V. infusion 400 mg in 16 mL) RO
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CETUXIMAB

Authority Required

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 TGA-approved Product Information.

Note

No applications for repeats will be authorised.

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Authority Required

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.

Note

No applications for repeats will be authorised.

7223E	Injection	880 mg	0	-	3210.29	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL) Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG SG
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CETUXIMAB

Authority Required

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.

Note

A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted.

7240C	Injection	550 mg	5	-	2167.84	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL) Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG SG
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CETUXIMAB

Authority Required

Initial PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with a WHO performance status of 2 or less and with K-RAS wild type metastatic colorectal cancer after failure of first-line chemotherapy.

Note

Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.

Note

Special Pricing Arrangements apply.

7242E	Injection	880 mg	0	-	3210.29	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL) Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG SG
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CETUXIMAB

Authority Required

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.

Note

Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.

Note

Special Pricing Arrangements apply.

7273T	Injection	550 mg	11	-	2167.84	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL) Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG SG
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RITUXIMAB

Authority Required

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma.

Authority Required

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma.

7257Y	Injection	800 mg	3	-	3758.15	34.20	Mabthera (Solution for I.V. infusion 100 mg in 10 mL) Mabthera (Solution for I.V. infusion 500 mg in 50 mL)	RO RO
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Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	
RITUXIMAB							
Authority Required							
Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.							
Authority Required							
Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.							
7258B	Injection	800 mg	7	-	3758.15	34.20	Mabthera (Solution for I.V. infusion 100 mg in 10 mL) RO Mabthera (Solution for I.V. infusion 500 mg in 50 mL) RO

RITUXIMAB

Authority Required

CD20 positive, chronic lymphocytic leukaemia, in combination with chemotherapy.

Note

Rituximab is not PBS-subsidised for use in monotherapy.

7259C	Injection	1100 mg	5	-	5108.05	34.20	Mabthera (Solution for I.V. infusion 100 mg in 10 mL) RO Mabthera (Solution for I.V. infusion 500 mg in 50 mL) RO
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TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

Initial treatment (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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] 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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].
- 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.

7264H	Injection	500 mg	0	-	3612.32	34.20	Herceptin (Powder for I.V. infusion 150 mg) RO Herceptin (Powder for I.V. infusion 60 mg) RO
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TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Chemotherapy Items for Private Hospital/Private Clinic use

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Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

7265J	Injection	250 mg	9	-	1965.54	34.20	Herceptin (Powder for I.V. infusion 150 mg) Herceptin (Powder for I.V. infusion 60 mg)	RO RO
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TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] 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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

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.

7266K	Injection	1000 mg	0	-	7119.55	34.20	Herceptin (Powder for I.V. infusion 150 mg) Herceptin (Powder for I.V. infusion 60 mg)	RO RO
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TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

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 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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

7267L	Injection	750 mg	3	-	5264.98	34.20	Herceptin (Powder for I.V. infusion 150 mg) Herceptin (Powder for I.V. infusion 60 mg)	RO RO
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Other antineoplastic agents

ARSENIC TRIOXIDE

Authority Required

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.

7241D	Injection	18 mg	89	-	908.89	34.20	Phenasen (Injection concentrate 10 mg in 10 mL)	PL
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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority Required

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 and who has undergone or is ineligible for a primary stem cell transplant. The patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease.

Chemotherapy Items for Private Hospital/Private Clinic use

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If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

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.

Any queries concerning additional details about treatment failure may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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.

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 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.

To enable confirmation by Medicare Australia, 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. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided.

Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (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

- (3) duration of thalidomide and daily dose prescribed; and
- (4) a signed patient acknowledgment.

Authority Required

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 4 treatment cycles of bortezomib 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

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7268M	Injection	3000 mcg	15	-	1875.92	34.20	Velcade (Powder for injection 3.5 mg) JC

(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. MRI or CT-Scan); or
 (g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

For the purpose of assessing eligibility for continuing 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
 Prior Written Approval of Specialised Drugs
 Reply Paid 9826
 GPO Box 9826
 HOBART TAS 7001

Authority Required

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 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. MRI or CT-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 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

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Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles per treatment course will not be approved.

Note

Special Pricing Arrangements apply.

7269N	Injection	3000 mcg	11	-	1875.92	34.20	Velcade (Powder for injection 3.5 mg)	JC
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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority Required

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 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
- (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. MRI or CT-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
- (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 Medicare Australia.

To enable confirmation by Medicare Australia, 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. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

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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.

Authority Required

Continuing retreatment of a patient who has been previously treated with 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. MRI or CT-Scan); or
- (g) normalisation of corrected serum calcium to less than or equal to 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

7271Q	Injection	3000 mcg	15	-	1875.92	34.20	Velcade (Powder for injection 3.5 mg)	JC
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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Authority Required

Continuing retreatment of a patient who has been previously treated with 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. MRI or CT-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 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

7272R	Injection	3000 mcg	11	-	1875.92	34.20	Velcade (Powder for injection 3.5 mg)	JC
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IRINOTECAN HYDROCHLORIDE TRIHYDRATE

Authority Required (STREAMLINED)

3184

Metastatic colorectal cancer in patients with a WHO performance status of 2 or less.

Note

In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.

7249M	Injection	800 mg	11	-	967.21	34.20	<ul style="list-style-type: none"> ^a Camptosar (I.V. injection 100 mg in 5 mL) PF ^a Camptosar (I.V. injection 300 mg in 15 mL) PF ^a Camptosar (I.V. injection 40 mg in 2 mL) PF ^a Hospira Pty Limited (I.V. injection 100 mg in 5 mL) HH ^a Hospira Pty Limited (I.V. injection 40 mg in 2 mL) HH ^a Hospira Pty Limited (I.V. injection 500 mg in 25 mL) HH ^a Irinotecan Actavis (I.V. injection 100 mg in 5 mL) TA ^a Irinotecan Actavis (I.V. injection 40 mg in 2 mL) TA ^a Irinotecan Actavis 500 (I.V. injection 500 mg in 25 mL) TA ^a Irinotecan Alphapharm (I.V. injection 100 mg in 5 mL) AF ^a Irinotecan Alphapharm (I.V. injection 40 mg in 2 mL) AF ^a Irinotecan Ebewe (I.V. injection 100 mg in 5 mL) SZ ^a Irinotecan Ebewe (I.V. injection 300 mg in 15 mL) SZ ^a Irinotecan Ebewe (I.V. injection 40 mg in 2 mL) SZ 	
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Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a Irinotecan Ebewe (I.V. injection 500 mg in 25 mL)	SZ
							^a Irinotecan Kabi (I.V. injection 100 mg in 5 mL)	PK
							^a Irinotecan Kabi (I.V. injection 40 mg in 2 mL)	PK
							^a Omegapharm Irinotecan (I.V. injection 100 mg in 5 mL)	OE
							^a Omegapharm Irinotecan (I.V. injection 40 mg in 2 mL)	OE
							^a Tecan (I.V. injection 100 mg in 5 mL)	WQ
							^a Tecan (I.V. injection 40 mg in 2 mL)	WQ

TOPOTECAN HYDROCHLORIDE

Authority Required (STREAMLINED)

3186

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.

7260D	Injection	3500 mcg	17	-	489.17	34.20	Hycamtin (Powder for I.V. infusion 4 mg (base))	GK
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CHEMOTHERAPY ITEMS FOR PUBLIC HOSPITAL USE

Special Pharmaceutical Benefits for Public Hospital use

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 28, in the Schedule of Pharmaceutical Benefits.

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Proposed Dispensed Price for Max. Amount	Total Dispensed Price for Max. Amount	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Antineoplastic and immunomodulating agents

Antineoplastic agents

Cytotoxic antibiotics and related substances

Other cytotoxic antibiotics

BLEOMYCIN SULFATE

Restricted Benefit

Germ cell neoplasms.

Restricted Benefit

Lymphoma.

4433H	Injection	30000 i.u.	11	\$73.56	121.78	195.34	34.20	Hospira Pty Limited (Powder for injection 15,000 i.u.)	HH
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Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Antineoplastic and immunomodulating agents

Antineoplastic agents

Alkylating agents

Nitrogen mustard analogues

CYCLOPHOSPHAMIDE

4327R	Injection	2800 mg	17	-	103.63	34.20	Endoxan (Powder for injection 1 g)	BX
							Endoxan (Powder for injection 2 g)	BX
							Endoxan (Powder for injection 500 mg)	BX

IFOSFAMIDE

Restricted Benefit

Relapsed or refractory germ cell tumours following first-line chemotherapy.

Restricted Benefit

Relapsed or refractory sarcomas following first-line chemotherapy.

4448D	Injection	4000 mg	19	-	276.60	34.20	Holoxan (Powder for I.V. injection 1 g)	BX
							Holoxan (Powder for I.V. injection 2 g)	BX

Nitrosoureas

FOTEMUSTINE

Authority Required (STREAMLINED)

3181

Metastatic malignant melanoma.

4437M	Injection	220 mg	8	-	2208.66	34.20	Muphoran (Powder for injection 208 mg with solvent)	SE
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Antimetabolites

Folic acid analogues

METHOTREXATE

4502Y	Injection	250 mg	5	-	63.55	34.20	Hospira Pty Limited (Injection 5 mg in 2 mL)	HH
							Hospira Pty Limited (Solution concentrate for I.V. infusion 500 mg in 20 mL)	HH
							Methotrexate Ebewe (Solution concentrate for I.V. infusion 5000 mg in 50 mL)	SZ
							^a Hospira Pty Limited (Injection 50 mg in 2 mL)	HH
							^a Hospira Pty Limited (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	HH
							^a Methotrexate Ebewe (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	SZ
							^a Pfizer Australia Pty Ltd (Injection 50 mg in 2 mL)	PF

METHOTREXATE

Restricted Benefit

Patients receiving treatment with a high dose regimen.

4512L	Injection	20000 mg	0	-	1924.00	34.20	Hospira Pty Limited (Injection 5 mg in 2 mL)	HH
							Hospira Pty Limited (Solution concentrate for I.V. infusion 500 mg in 20 mL)	HH
							Methotrexate Ebewe (Solution concentrate for I.V. infusion 5000 mg in 50 mL)	SZ
							^a Hospira Pty Limited (Injection 50 mg in 2 mL)	HH
							^a Hospira Pty Limited (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	HH
							^a Methotrexate Ebewe (Solution concentrate for I.V. infusion 1000 mg in 10 mL)	SZ

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	
							^a Pfizer Australia Pty Ltd (Injection 50 mg in 2 mL) PF

PEMETREXED DISODIUM

Authority Required (STREAMLINED)

3885

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.

Doses greater than 500 mg per metre squared body surface area (BSA) are not PBS-subsidised. The patient's BSA must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority Required (STREAMLINED)

3886

Mesothelioma in combination with cisplatin. Doses greater than 500 mg per metre squared body surface area (BSA) are not PBS-subsidised. The patient's BSA must be documented in the patient's medical records at the time the treatment cycle is initiated.

Note

No applications for increased maximum quantities for the 500 mg vial will be authorised.

4600D	Injection	1100 mg	5	-	3471.67	34.20	Alimta (Powder for I.V. infusion 100 mg (base)) LY Alimta (Powder for I.V. infusion 500 mg (base)) LY
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RALTITREXED

Authority Required (STREAMLINED)

3185

For use as a single agent in the treatment of advanced colorectal cancer.

4610P	Injection	7 mg	8	-	1053.36	34.20	Tomudex (Powder for I.V. infusion 2 mg) HH
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Purine analogues

CLADRIBINE

Authority Required (STREAMLINED)

3180

Hairy cell leukaemia.

4326Q	Injection	17 mg	6	-	1320.92	34.20	Leustatin (Solution for I.V. infusion 10 mg in 10 mL) JC Litak (Injection 10 mg in 5 mL) OA
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FLUDARABINE PHOSPHATE

Authority Required (STREAMLINED)

3887

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.

Stage A progressive disease is defined by at least one 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.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:

- (a) a lymphocytosis, with more than 5000 million lymphocytes per L in the peripheral blood; and
- (b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.

Note

Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical benefits that have the form fludarabine phosphate solution for I.V. injection 50 mg are equivalent for the purposes of substitution.

4393F	Injection	55 mg	29	-	588.48	34.20	^a Farine (Powder for I.V. injection 50 mg) WQ ^a Fludara (Powder for I.V. injection 50 mg) GZ ^a Fludarabine Actavis (Powder for I.V. injection 50 mg) TA ^a Fludarabine Ebewe (Solution for I.V. injection 50 mg in 2 mL) SZ
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Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
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Pyrimidine analogues

CYTARABINE								
4357H	Injection	7000 mg	15	-	746.30	34.20	Pfizer Australia Pty Ltd (Injection 100 mg in 5 mL)	PF

FLUOROURACIL

Restricted Benefit

For patients requiring administration of fluorouracil by intravenous infusion.

4394G	Injection	5500 mg	11	-	78.17	34.20	Fluorouracil Ebewe (Injection 5000 mg in 100 mL)	SZ
							^a DBL Fluorouracil Injection BP (Injection 1000 mg in 20 mL)	HH
							^a DBL Fluorouracil Injection BP (Injection 2500 mg in 50 mL)	HH
							^a Fluorouracil Ebewe (Injection 1000 mg in 20 mL)	SZ
							^a Fluorouracil Ebewe (Injection 2500 mg in 50 mL)	SZ
							^a Fluorouracil Ebewe (Injection 500 mg in 10 mL)	SZ
							^a Hospira Pty Limited (Injection 500 mg in 10 mL)	HH

FLUOROURACIL

Restricted Benefit

For patients requiring administration of fluorouracil by intravenous injection.

4431F	Injection	1000 mg	23	-	46.94	34.20	Fluorouracil Ebewe (Injection 5000 mg in 100 mL)	SZ
							^a DBL Fluorouracil Injection BP (Injection 1000 mg in 20 mL)	HH
							^a DBL Fluorouracil Injection BP (Injection 2500 mg in 50 mL)	HH
							^a Fluorouracil Ebewe (Injection 1000 mg in 20 mL)	SZ
							^a Fluorouracil Ebewe (Injection 2500 mg in 50 mL)	SZ
							^a Fluorouracil Ebewe (Injection 500 mg in 10 mL)	SZ
							^a Hospira Pty Limited (Injection 500 mg in 10 mL)	HH

GEMCITABINE

Authority Required (STREAMLINED)

3889

Locally advanced or metastatic adenocarcinoma of the pancreas.

Authority Required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority Required (STREAMLINED)

3906

Locally advanced or metastatic bladder cancer, in combination with cisplatin.

Authority Required (STREAMLINED)

3913

Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline.

Authority Required (STREAMLINED)

3914

Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy.

Note

Pharmaceutical benefits that have the form gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) are equivalent for the purposes of substitution.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
4439P	Injection	3000 mg	17	-	433.60	34.20	Gemcitabine Ebewe (Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL)	SZ
							^a DBL Gemcitabine for Injection (Powder for I.V. infusion 1 g (as hydrochloride))	HH
							^a DBL Gemcitabine for Injection (Powder for I.V. infusion 2 g (as hydrochloride))	HH
							^a DBL Gemcitabine for Injection (Powder for I.V. infusion 200 mg (as hydrochloride))	HH
							^a Gemcitabine Actavis (Powder for I.V. infusion 1 g (as hydrochloride))	TA
							^a Gemcitabine Actavis (Powder for I.V. infusion 200 mg (as hydrochloride))	TA
							^a Gemcitabine Ebewe (Powder for I.V. infusion 1 g (as hydrochloride))	SZ
							^a Gemcitabine Ebewe (Powder for I.V. infusion 200 mg (as hydrochloride))	SZ
							^a Gemcitabine Ebewe (Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL)	SZ
							^a Gemcitabine Ebewe (Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL)	SZ
							^a Gemcitabine Kabi (Powder for I.V. infusion 1 g (as hydrochloride))	PK
							^a Gemcitabine Kabi (Powder for I.V. infusion 2 g (as hydrochloride))	PK
							^a Gemcitabine Kabi (Powder for I.V. infusion 200 mg (as hydrochloride))	PK
							^a Gemcitabine Sun (Powder for I.V. infusion 1 g (as hydrochloride))	ZF
							^a Gemcitabine Sun (Powder for I.V. infusion 200 mg (as hydrochloride))	ZF
							^a Gemcite (Powder for I.V. infusion 1 g (as hydrochloride))	ZP
							^a Gemcite (Powder for I.V. infusion 200 mg (as hydrochloride))	ZP
							^a Gemplan (Powder for I.V. infusion 1 g (as hydrochloride))	WQ
							^a Gemplan (Powder for I.V. infusion 200 mg (as hydrochloride))	WQ
							^a Gemzar (Powder for I.V. infusion 1 g (as hydrochloride))	LY
							^a Gemzar (Powder for I.V. infusion 200 mg (as hydrochloride))	LY

Plant alkaloids and other natural products *Vinca alkaloids and analogues*

VINBLASTINE SULFATE								
4618C	Injection	20 mg	17	-	95.24	34.20	Hospira Pty Limited (Solution for I.V. injection 10 mg in 10 mL)	HH
VINCRIStINE SULFATE								
4619D	Injection	2 mg	7	-	64.66	34.20	^a Hospira Pty Limited (I.V. injection 1 mg in 1 mL)	HH
							^a Pfizer Australia Pty Ltd (I.V. injection 1 mg in 1 mL)	PF
VINORELBINE								
<u>Authority Required (STREAMLINED)</u>								
3890								
Locally advanced or metastatic non-small cell lung cancer.								
<u>Authority Required (STREAMLINED)</u>								
3907								
Advanced breast cancer after failure of prior therapy which includes an anthracycline.								
4620E	Injection	70 mg	7	-	424.84	34.20	^a Hospira Pty Limited (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	HH
							^a Hospira Pty Limited (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	HH

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a Navelbine (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	FB
							^a Navelbine (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	FB
							^a Vinorelbine Ebewe (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	SZ
							^a Vinorelbine Ebewe (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	SZ
							^a Vinorelbine Kabi (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	PK

Podophyllotoxin derivatives

ETOPOSIDE								
4428C	Injection	440 mg	14	-	172.80	34.20	Etopophos (Powder for I.V. infusion 1 g (as phosphate))	BQ
							Etopophos (Powder for I.V. infusion 100 mg (as phosphate))	BQ
							^a Etoposide Ebewe (Solution for I.V. infusion 100 mg in 5 mL)	SZ
							^a Hospira Pty Limited (Solution for I.V. infusion 100 mg in 5 mL)	HH

Taxanes

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3916

Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

5581R	Injection	250 mg	5	-	3783.04	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL)	HH
							Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL)	TA
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HH
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HH
							^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HX
							^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HX
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL)	SZ
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL)	SZ
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3918

Treatment of HER2 positive early breast cancer in combination with trastuzumab.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

5582T	Injection	250 mg	5	-	3783.04	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL)	HH
							Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL)	TA
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HH
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HH
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL)	SZ
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL)	SZ
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3888

Neoadjuvant treatment of a patient with a WHO 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.

Note

The carcinoma can be considered inoperable for technical or organ preservation reasons.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

5583W	Injection	250 mg	5	-	3783.04	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL)	HH
							Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL)	TA

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HH
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HH
							^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HX
							^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HX
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL)	SZ
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL)	SZ
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority Required (STREAMLINED)

3892

Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.

Note

A maximum of four cycles of treatment will be authorised under this restriction.

Note

Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.

5584X	Injection	250 mg	5	-	3783.04	34.20	Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL)	TA
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	
<u>Authority Required (STREAMLINED)</u>							
3890							
Locally advanced or metastatic non-small cell lung cancer.							
<u>Authority Required (STREAMLINED)</u>							
3186							
Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.							
<u>Authority Required (STREAMLINED)</u>							
3884							
Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.							
<u>Note</u>							
A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.							
<u>Authority Required (STREAMLINED)</u>							
3893							
Advanced breast cancer after failure of prior therapy.							
<u>Note</u>							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and 20 mg in 2 mL, docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) and docetaxel powder for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.							
<u>Note</u>							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and 80 mg in 8 mL, docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) and docetaxel powder for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.							
5585Y	Injection	250 mg	5	-	3783.04	34.20	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) HH Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) TA ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) HH ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL) HH ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL) HX ^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL) HX ^a Docetaxel SUN (Powder for I.V. infusion 20 mg with solvent) ZF ^a Docetaxel SUN (Powder for I.V. infusion 80 mg with solvent) ZF ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL) SZ ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL) SZ ^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL) TA ^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL) TA ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent) SW ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent) SW ^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL) SW ^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL) SW
NAB PACLITAXEL							
<u>Authority Required (STREAMLINED)</u>							
3897							
Metastatic breast cancer after failure of prior therapy.							
4531L	Injection	580 mg	5	-	2448.88	34.20	Abraxane (Powder for I.V. injection 100 mg (base)) TS

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
PACLITAXEL							
<u>Authority Required (STREAMLINED)</u>							
3890							
Locally advanced or metastatic non-small cell lung cancer.							
<u>Authority Required (STREAMLINED)</u>							
3902							
Primary treatment of ovarian cancer in combination with a platinum compound.							
<u>Authority Required (STREAMLINED)</u>							
3186							
Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.							
<u>Authority Required (STREAMLINED)</u>							
3917							
Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide.							
<u>Authority Required (STREAMLINED)</u>							
3918							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<u>Authority Required (STREAMLINED)</u>							
3893							
Advanced breast cancer after failure of prior therapy.							
4567J	Injection	450 mg	3	-	1178.56	34.20	a Anzatax (Solution concentrate for I.V. infusion 100 mg in 16.7 mL) HH a Anzatax (Solution concentrate for I.V. infusion 150 mg in 25 mL) HH a Anzatax (Solution concentrate for I.V. infusion 30 mg in 5 mL) HH a Anzatax (Solution concentrate for I.V. infusion 300 mg in 50 mL) HH a Paclitaxel Actavis (Solution concentrate for I.V. infusion 100 mg in 16.7 mL) TA a Paclitaxel Actavis (Solution concentrate for I.V. infusion 150 mg in 25 mL) TA a Paclitaxel Actavis (Solution concentrate for I.V. infusion 30 mg in 5 mL) TA a Paclitaxel Actavis (Solution concentrate for I.V. infusion 300 mg in 50 mL) TA a Paclitaxel Ebewe (Solution concentrate for I.V. infusion 100 mg in 16.7 mL) SZ a Paclitaxel Ebewe (Solution concentrate for I.V. infusion 150 mg in 25 mL) SZ a Paclitaxel Ebewe (Solution concentrate for I.V. infusion 30 mg in 5 mL) SZ a Paclitaxel Ebewe (Solution concentrate for I.V. infusion 300 mg in 50 mL) SZ a Paclitaxel Kabi (Solution concentrate for I.V. infusion 100 mg in 16.7 mL) PK a Paclitaxel Kabi (Solution concentrate for I.V. infusion 30 mg in 5 mL) PK a Paclitaxel Kabi (Solution concentrate for I.V. infusion 300 mg in 50 mL) PK a Plaxel (Solution concentrate for I.V. infusion 100 mg in 16.7 mL) WQ a Plaxel (Solution concentrate for I.V. infusion 150 mg in 25 mL) WQ a Plaxel (Solution concentrate for I.V. infusion 30 mg in 5 mL) WQ a Plaxel (Solution concentrate for I.V. infusion 300 mg in 50 mL) WQ a Taxol (Solution concentrate for I.V. infusion 100 mg in 16.7 mL) BQ a Taxol (Solution concentrate for I.V. infusion 30 mg in 5 mL) BQ a Taxol (Solution concentrate for I.V. infusion 300 mg in 50 mL) BQ

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
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Cytotoxic antibiotics and related substances Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE

4361M	Injection/intravesical	135 mg	11	-	122.74	34.20	Adriamycin Solution (Solution for I.V. injection or intravesical administration 20 mg in 10 mL) PF Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 100 mg in 50 mL) SZ ^a Adriamycin (Solution for I.V. injection or intravesical administration 200 mg in 100 mL) PF ^a Adriamycin Solution (Solution for I.V. injection or intravesical administration 10 mg in 5 mL) PF ^a Adriamycin Solution (Solution for I.V. injection or intravesical administration 50 mg in 25 mL) PF ^a Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 10 mg in 5 mL) SZ ^a Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 200 mg in 100 mL) SZ ^a Doxorubicin Ebewe (Solution for I.V. injection or intravesical administration 50 mg in 25 mL) SZ ^a Hospira Pty Limited (Solution for I.V. injection or intravesical administration 10 mg in 5 mL) HH ^a Hospira Pty Limited (Solution for I.V. injection or intravesical administration 50 mg in 25 mL) HH
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DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL

Authority Required (STREAMLINED)

3905

Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.

Authority Required (STREAMLINED)

3910

Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane.

Authority Required (STREAMLINED)

3911

Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.

4364Q	Injection	100 mg	5	-	3006.60	34.20	Caelyx (Suspension for I.V. infusion 20 mg in 10 mL) JC Caelyx (Suspension for I.V. infusion 50 mg in 25 mL) JC
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EPIRUBICIN HYDROCHLORIDE

4375G	Injection/intravesical	220 mg	5	-	775.57	34.20	Pharmorubicin Solution (Solution for injection 20 mg in 10 mL) PF ^a DBL Epirubicin Hydrochloride Injection (Solution for injection 200 mg in 100 mL) HH ^a Epirubicin Ebewe (Solution for injection 10 mg in 5 mL) SZ ^a Epirubicin Ebewe (Solution for injection 100 mg in 50 mL) SZ ^a Epirubicin Ebewe (Solution for injection 200 mg in 100 mL) SZ ^a Epirubicin Ebewe (Solution for injection 50 mg in 25 mL) SZ ^a Hospira Pty Limited (Solution for injection 100 mg in 50 mL) HH ^a Hospira Pty Limited (Solution for injection 50 mg in 25 mL) HH ^a Pharmorubicin Solution (Solution for injection 10 mg in 5 mL) PF ^a Pharmorubicin Solution (Solution for injection 50 mg in 25 mL) PF
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IDARUBICIN HYDROCHLORIDE

Restricted Benefit

Acute myelogenous leukaemia.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
4440Q	Injection	30 mg	5	-	856.93	34.20	^a Idarubicin Ebewe (Solution for I.V. injection 10 mg in 10 mL) SZ
							^a Idarubicin Ebewe (Solution for I.V. injection 5 mg in 5 mL) SZ
							^a Zavedos Solution (Solution for I.V. injection 10 mg in 10 mL) PF
							^a Zavedos Solution (Solution for I.V. injection 5 mg in 5 mL) PF
MITOZANTRONE HYDROCHLORIDE							
4514N	Injection	30 mg	5	-	235.75	34.20	Pfizer Australia Pty Ltd (Injection 10 mg (base) in 5 mL) PF
							^a Hospira Pty Limited (Injection 20 mg (base) in 10 mL) HH
							^a Mitozantrone Ebewe (Injection 20 mg (base) in 10 mL) SZ
							^a Onkotrone (Injection 20 mg (base) in 10 mL) BX
							^a Onkotrone (Injection 25 mg (base) in 12.5 mL) BX
							^a Pfizer Australia Pty Ltd (Injection 20 mg (base) in 10 mL) PF
							^a Pfizer Australia Pty Ltd (Injection 25 mg (base) in 12.5 mL) PF

Other antineoplastic agents *Platinum compounds*

CARBOPLATIN							
4309T	Injection	900 mg	5	-	264.06	34.20	^a Carboplatin Ebewe (Solution for I.V. injection 150 mg in 15 mL) SZ
							^a Carboplatin Ebewe (Solution for I.V. injection 450 mg in 45 mL) SZ
							^a Carboplatin Ebewe (Solution for I.V. injection 50 mg in 5 mL) SZ
							^a Hospira Pty Limited (Solution for I.V. injection 150 mg in 15 mL) HH
							^a Hospira Pty Limited (Solution for I.V. injection 450 mg in 45 mL) HH
							^a Hospira Pty Limited (Solution for I.V. injection 50 mg in 5 mL) HH
							^a Pfizer Australia Pty Ltd (Solution for I.V. injection 150 mg in 15 mL) PF
							^a Pfizer Australia Pty Ltd (Solution for I.V. injection 450 mg in 45 mL) PF
							^a Pfizer Australia Pty Ltd (Solution for I.V. injection 50 mg in 5 mL) PF

CISPLATIN							
4319H	Injection	220 mg	14	-	90.82	34.20	Pfizer Australia Pty Ltd (I.V. injection 10 mg in 10 mL) PF
							^a Cisplatin Ebewe (I.V. injection 100 mg in 100 mL) SZ
							^a Hospira Pty Limited (I.V. injection 100 mg in 100 mL) HH
							^a Hospira Pty Limited (I.V. injection 50 mg in 50 mL) HH
							^a Pfizer Australia Pty Ltd (I.V. injection 100 mg in 100 mL) PF
							^a Pfizer Australia Pty Ltd (I.V. injection 50 mg in 50 mL) PF

OXALIPLATIN

Authority Required (STREAMLINED)

3930

Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with capecitabine.

Authority Required (STREAMLINED)

3939

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.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
<u>Authority Required (STREAMLINED)</u>							
3900							
Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with capecitabine.							
<u>Authority Required (STREAMLINED)</u>							
3901							
Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with 5-fluorouracil and folinic acid.							
<u>Note</u>							
Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer. Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.							
<u>Note</u>							
Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 50 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 50 mg are equivalent for the purposes of substitution.							
<u>Note</u>							
Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 100 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 100 mg are equivalent for the purposes of substitution.							
4542C	Injection	300 mg	11	-	531.04	34.20	a DBL Oxaliplatin Concentrate (Solution concentrate for I.V. infusion 100 mg in 20 mL) HH a DBL Oxaliplatin Concentrate (Solution concentrate for I.V. infusion 50 mg in 10 mL) HH a Eloxatin (Solution concentrate for I.V. infusion 100 mg in 20 mL) SW a Eloxatin (Solution concentrate for I.V. infusion 200 mg in 40 mL) SW a Eloxatin (Solution concentrate for I.V. infusion 50 mg in 10 mL) SW a Hospira Pty Limited (Powder for I.V. infusion 100 mg) HH a Hospira Pty Limited (Powder for I.V. infusion 50 mg) HH a Oxalatin (Powder for I.V. infusion 100 mg) ZP a Oxalatin (Powder for I.V. infusion 50 mg) ZP a Oxaliplatin Actavis (Powder for I.V. infusion 100 mg) TA a Oxaliplatin Actavis (Powder for I.V. infusion 50 mg) TA a Oxaliplatin Alphapharm (Powder for I.V. infusion 100 mg) AF a Oxaliplatin Alphapharm (Powder for I.V. infusion 50 mg) AF a Oxaliplatin Ebewe (Powder for I.V. infusion 100 mg) SZ a Oxaliplatin Ebewe (Powder for I.V. infusion 50 mg) SZ a Oxaliplatin Kabi (Solution concentrate for I.V. infusion 100 mg in 20 mL) PK a Oxaliplatin Kabi (Solution concentrate for I.V. infusion 50 mg in 10 mL) PK a Oxaliplatin Link (Powder for I.V. infusion 100 mg) PK a Oxaliplatin Link (Powder for I.V. infusion 50 mg) PK a Oxaliplatin SUN (Solution concentrate for I.V. infusion 100 mg in 20 mL) ZF a Oxaliplatin SUN (Solution concentrate for I.V. infusion 200 mg in 40 mL) ZF a Oxaliplatin SUN (Solution concentrate for I.V. infusion 50 mg in 10 mL) ZF a Winthrop Oxaliplatin (Powder for I.V. infusion 100 mg) WA a Xalox (Powder for I.V. infusion 100 mg) WQ a Xalox (Powder for I.V. infusion 50 mg) WQ

Monoclonal antibodies

BEVACIZUMAB

Authority Required (STREAMLINED)

3894

Initial PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with previously untreated metastatic colorectal cancer with a WHO performance status of 0 or 1.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	

Doses greater than 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks will not be PBS-subsidised. The patient's WHO performance status and body weight must be recorded in the patient's medical records at the time the treatment cycle is initiated.

Note

Not for use as monotherapy.

Authority Required (STREAMLINED)

3896

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.

Doses greater than 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks will not be PBS-subsidised. The patient's body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Note

Not for use as monotherapy.

Note

Special Pricing Arrangements apply.

4400N	Injection	900 mg	11	-	3952.50	34.20	Avastin (Solution for I.V. infusion 100 mg in 4 mL)	RO
							Avastin (Solution for I.V. infusion 400 mg in 16 mL)	RO

CETUXIMAB

Authority Required (STREAMLINED)

3919

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 TGA-approved Product Information.

Note

No applications for repeats will be authorised.

Authority Required (STREAMLINED)

3920

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.

Note

No applications for repeats will be authorised.

4312Y	Injection	880 mg	0	-	3109.00	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL)	SG
							Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG

CETUXIMAB

Authority Required (STREAMLINED)

3921

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.

Note

A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted.

4435K	Injection	550 mg	5	-	2086.00	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL)	SG
							Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG

CETUXIMAB

Authority Required (STREAMLINED)

3903

Initial PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with a WHO performance status of 2 or less and with K-RAS wild type metastatic colorectal cancer after failure of first-line chemotherapy.

Note

Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.

Note

Special Pricing Arrangements apply.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
4436L	Injection	880 mg	0	-	3109.00	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL) Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG SG

CETUXIMAB

Authority Required (STREAMLINED)

3904

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.

Note

Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.

Note

Special Pricing Arrangements apply.

4731B	Injection	550 mg	11	-	2086.00	34.20	Erbix (Solution for I.V. infusion 100 mg in 20 mL) Erbix (Solution for I.V. infusion 500 mg in 100 mL)	SG SG
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RITUXIMAB

Authority Required (STREAMLINED)

3912

Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.

Authority Required (STREAMLINED)

3915

Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.

4613T	Injection	800 mg	7	-	3661.73	34.20	Mabthera (Solution for I.V. infusion 100 mg in 10 mL) Mabthera (Solution for I.V. infusion 500 mg in 50 mL)	RO RO
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RITUXIMAB

Authority Required (STREAMLINED)

3908

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma.

Authority Required (STREAMLINED)

3909

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma.

4614W	Injection	800 mg	3	-	3661.73	34.20	Mabthera (Solution for I.V. infusion 100 mg in 10 mL) Mabthera (Solution for I.V. infusion 500 mg in 50 mL)	RO RO
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RITUXIMAB

Authority Required (STREAMLINED)

3932

CD20 positive, chronic lymphocytic leukaemia, in combination with chemotherapy.

Note

Rituximab is not PBS-subsidised for use in monotherapy.

4615X	Injection	1100 mg	5	-	5019.86	34.20	Mabthera (Solution for I.V. infusion 100 mg in 10 mL) Mabthera (Solution for I.V. infusion 500 mg in 50 mL)	RO RO
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TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer	
					Price for Max. Amount \$	Recordable Value for Safety Net \$		
4632T	Injection	500 mg	0	-	3542.69	34.20	Herceptin (Powder for I.V. infusion 150 mg) Herceptin (Powder for I.V. infusion 60 mg)	RO RO

TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer	
					Price for Max. Amount \$	Recordable Value for Safety Net \$		
4639E	Injection	250 mg	9	-	1894.37	34.20	Herceptin (Powder for I.V. infusion 150 mg)	RO
							Herceptin (Powder for I.V. infusion 60 mg)	RO

TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] 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 [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].
- 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.

4650R	Injection	1000 mg	0	-	7045.36	34.20	Herceptin (Powder for I.V. infusion 150 mg)	RO
							Herceptin (Powder for I.V. infusion 60 mg)	RO

TRASTUZUMAB

Note

Any queries concerning the arrangements to prescribe trastuzumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe trastuzumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Authority Required

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 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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer	
					Price for Max. Amount \$	Recordable Value for Safety Net \$		
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 on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
4703M	Injection	750 mg	3	-	5191.01	34.20	Herceptin (Powder for I.V. infusion 150 mg) Herceptin (Powder for I.V. infusion 60 mg)	RO RO

Other antineoplastic agents

ARSENIC TRIOXIDE

Authority Required (STREAMLINED)

3891

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.

4371C	Injection	18 mg	89	-	841.66	34.20	Phenasen (Injection concentrate 10 mg in 10 mL)	PL
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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority Required

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 and who has undergone or is ineligible for a primary stem cell transplant. The patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

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.

Any queries concerning additional details about treatment failure may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Chemotherapy Items for Public Hospital use

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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.

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 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.

To enable confirmation by Medicare Australia, 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. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided.

Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (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

- (3) duration of thalidomide and daily dose prescribed; and
- (4) a signed patient acknowledgment.

Authority Required

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 4 treatment cycles of bortezomib 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. MRI or CT-Scan); or
- (g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

For the purpose of assessing eligibility for continuing 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

4706Q	Injection	3000 mcg	15	-	1771.49	34.20	Velcade (Powder for injection 3.5 mg)	JC
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Chemotherapy Items for Public Hospital use

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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority Required

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 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. MRI or CT-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 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

4712B	Injection	3000 mcg	11	-	1771.49	34.20	Velcade (Powder for injection 3.5 mg)	JC
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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826

Chemotherapy Items for Public Hospital use

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					Price for Max. Amount \$	Recordable Value for Safety Net \$	
	GPO Box 9826 HOBART TAS 7001						

Authority Required

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 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
- (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. MRI or CT-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
- (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 Medicare Australia.

To enable confirmation by Medicare Australia, 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. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided.

Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (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.

Authority Required

Continuing retreatment of a patient who has been previously treated with 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:

Chemotherapy Items for Public Hospital use

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					Price for Max. Amount \$	Recordable Value for Safety Net \$	

- (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. MRI or CT-Scan); or
 (g) normalisation of corrected serum calcium to less than or equal to 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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

4713C	Injection	3000 mcg	15	-	1771.49	34.20	Velcade (Powder for injection 3.5 mg)	JC
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BORTEZOMIB

Note

Any queries concerning the arrangements to prescribe bortezomib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe bortezomib should be forwarded to:

Medicare Australia
 Prior Written Approval of Specialised Drugs
 Reply Paid 9826
 GPO Box 9826
 HOBART TAS 7001

Authority Required

Continuing retreatment of a patient who has been previously treated with 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. MRI or CT-Scan); or
 (g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Chemotherapy Items for Public Hospital use

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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 Medicare Australia for further treatment. Where a response assessment is not submitted to Medicare Australia 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.

Note

Special Pricing Arrangements apply.

4725Q	Injection	3000 mcg	11	-	1771.49	34.20	Velcade (Powder for injection 3.5 mg)	JC
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IRINOTECAN HYDROCHLORIDE TRIHYDRATE

Authority Required (STREAMLINED)

3184

Metastatic colorectal cancer in patients with a WHO performance status of 2 or less.

Note

In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.

4451G	Injection	800 mg	11	-	897.74	34.20	^a Camptosar (I.V. injection 100 mg in 5 mL) ^a Camptosar (I.V. injection 300 mg in 15 mL) ^a Camptosar (I.V. injection 40 mg in 2 mL) ^a Hospira Pty Limited (I.V. injection 100 mg in 5 mL) ^a Hospira Pty Limited (I.V. injection 40 mg in 2 mL) ^a Hospira Pty Limited (I.V. injection 500 mg in 25 mL) ^a Irinotecan Actavis (I.V. injection 100 mg in 5 mL) ^a Irinotecan Actavis (I.V. injection 40 mg in 2 mL) ^a Irinotecan Actavis 500 (I.V. injection 500 mg in 25 mL) ^a Irinotecan Alphapharm (I.V. injection 100 mg in 5 mL) ^a Irinotecan Alphapharm (I.V. injection 40 mg in 2 mL) ^a Irinotecan Ebewe (I.V. injection 100 mg in 5 mL) ^a Irinotecan Ebewe (I.V. injection 300 mg in 15 mL) ^a Irinotecan Ebewe (I.V. injection 40 mg in 2 mL) ^a Irinotecan Ebewe (I.V. injection 500 mg in 25 mL) ^a Irinotecan Kabi (I.V. injection 100 mg in 5 mL) ^a Irinotecan Kabi (I.V. injection 40 mg in 2 mL) ^a Omegapharm Irinotecan (I.V. injection 100 mg in 5 mL) ^a Omegapharm Irinotecan (I.V. injection 40 mg in 2 mL) ^a Tecan (I.V. injection 100 mg in 5 mL) ^a Tecan (I.V. injection 40 mg in 2 mL)	PF PF PF HH HH HH TA TA TA AF AF SZ SZ SZ SZ PK PK OE OE WQ WQ
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TOPOTECAN HYDROCHLORIDE

Authority Required (STREAMLINED)

3186

Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.

4617B	Injection	3500 mcg	17	-	436.00	34.20	Hycamtin (Powder for I.V. infusion 4 mg (base))	GK
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<i>Zavedos Solution (Solution for I.V. injection 5 mg in 5 mL) (PF)</i>	21, 45