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

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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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7275X, 4403R
4429P, 4732C

7268M, 7269N **Bortezomib,** bortezomib 3.5 mg injection, 1 x 3.5 mg vial
7271Q, 7272R
4706Q, 4712B
4713C, 4725Q

7264H, 7265J **Trastuzumab,** trastuzumab 60 mg injection, 1 x 60 mg vial

7266K, 7267L **Trastuzumab**, trastuzumab 150 mg injection, 1 x 150 mg vial
4632T,4639E
4650R, 4703M

Alteration – Manufacturer's Code

		From:	*To:*
5898K	*Kytril, RO* – **Granisetron**, granisetron 2 mg tablet, 1	HH	RO
5899L	*Kytril, RO* – **Granisetron**, granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule	HH	RO

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) came into effect on 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. The Revised Arrangements operate under a section 100 program which includes 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 Chemotherapy Pharmaceutical Access Program (CPAP).

This Schedule is split into two parts:

1) Chemotherapy items for private hospital/private clinic use

This includes items subject to the revised arrangements, ie. chemotherapy drugs administered through infusion or injection

2a) Chemotherapy items for public hospital use

This includes items subject to the revised arrangements, ie. chemotherapy drugs administered through infusion or injection

2b) Related pharmaceutical benefits (not subject to the revised arrangements) for public hospital use

This includes items such as antiemetics, antinauseants, immunostimulants and detoxifying agents for antineoplastic treatment

Where public hospital prescribers write prescriptions for chemotherapy infusibles, that are to be dispensed outside public hospitals, they will need to prescribe from the list of chemotherapy items for private hospital/private clinic use. In these circumstances any related pharmaceutical benefits will need to be prescribed using the General Schedule listings of these drugs. Any associated authority approvals would also need to be obtained.

Prescribing and Supplying - Information for PBS Prescribers and Pharmacists

NOTE: The following information relates only to chemotherapy items subject to the revised arrangements. The related pharmaceutical benefits listed in this Schedule primarily follow the same rules as those listed in the General Pharmaceutical Benefits Schedule.

Chemotherapy drugs are listed based on the relevant unit of measure. Prescribers of these 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 for a specific infusion/injection
- 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 on the recommendation of the prescriber without requirement for a new prescription.

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 ($6.52)
- Preparation fee ($40.64)
- Distribution fee ($24.38)
- Diluent fee ($4.83)

Section 94 Approved Public Hospital Authority

- Preparation fee ($40.64)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee ($6.52)
- Preparation fee ($40.64)
- Distribution fee ($24.38) (not payable where the drug is trastuzumab)
- Diluent fee ($4.83)

THERAPEUTIC INDEX

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 32.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Other cytotoxic antibiotics

BLEOMYCIN SULFATE

Restricted benefit
Germ cell neoplasms

Restricted benefit
Lymphoma

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Total Dispensed Price for Max. Amount $	Proposed Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
7244G	Injection	30000 iu	11	$67.94	*151.95	*219.89	35.40	Bleo 15K (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial) Hospira Pty Limited (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial)	WQ HH

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 Name and Manufacturer	
	ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS							
	ANTINEOPLASTIC AGENTS							
	ALKYLATING AGENTS							
	Nitrogen mustard analogues							
	CYCLOPHOSPHAMIDE							
7226H	Injection	2800 mg	17	..	*146.36	35.40	Endoxan (cyclophosphamide 1 g injection, 1 x 1 g vial)	BX
							Endoxan (cyclophosphamide 2 g injection, 1 x 2 g vial)	BX
							Endoxan (cyclophosphamide 500 mg injection, 1 x 500 mg vial)	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	..	*330.97	35.40	Holoxan (ifosfamide 1 g injection, 1 x 1 g vial)	BX
							Holoxan (ifosfamide 2 g injection, 1 x 2 g vial)	BX
	Nitrosoureas							
	FOTEMUSTINE							
	Authority required (STREAMLINED)							
	3181							
	Metastatic malignant melanoma							
7245H	Injection	220 mg	8	..	*2315.03	35.40	Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&) inert substance diluent [1 x 4 mL ampoule], 1 pack)	SE
	ANTIMETABOLITES							
	Folic acid analogues							
	METHOTREXATE							
7250N	Injection	250 mg	5	..	*97.97	35.40	Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	HH
							Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)	HH
							Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)	HH
							Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)	HH
							Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)	WQ
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	WQ
							Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)	PF
	METHOTREXATE							
	Restricted benefit							
	Patients receiving treatment with a high dose regimen.							
7251P	Injection	20000 mg	..	..	*1639.97	35.40	Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	HH
							Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)	HH
							Hospira Pty Limited (methotrexate 50 mg/2 mL	HH

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 Name and Manufacturer	
							injection, 5 x 2 mL vials)	
							Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)	HH
							Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)	WQ
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	WQ
							Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)	PF
	PEMETREXED **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							
7255W	Injection	1100 mg	5	..	*3561.08	35.40	Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial)	LY
							Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial)	LY
	RALTITREXED **Authority required (STREAMLINED)** ***3185*** For use as a single agent in the treatment of advanced colorectal cancer							
7256X	Injection	7 mg	8	..	*1130.25	35.40	Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial)	HH
	Purine analogues							
	CLADRIBINE **Authority required (STREAMLINED)** ***3180*** Hairy cell leukaemia							
7225G	Injection	17 mg	6	..	*1408.53	35.40	Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial)	JC
							Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial)	OA
	FLUDARABINE **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 5,000 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	..	*646.79	35.40	Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	WQ
							Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)	GZ

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 Name and Manufacturer	
							Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	TA
							Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)	SZ

Pyrimidine analogues

CYTARABINE

7227J	Injection	7000 mg	15	..	*810.67	35.40	Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)	PF

FLUOROURACIL

Restricted benefit

For patients requiring administration of fluorouracil by intravenous infusion.

7234R	Injection	5500 mg	11	..	*118.53	35.40	DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)	HH
							DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	HH
							Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH

FLUOROURACIL

Restricted benefit

For patients requiring administration of fluorouracil by intravenous injection.

7239B	Injection	1000 mg	23	..	*84.35	35.40	DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)	HH
							DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	HH
							Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH

GEMCITABINE

Caution

Pharmaceutical benefits containing gemcitabine may have different concentrations.

Note

Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL, gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL and gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL and gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL, gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL and gemcitabine solution for injection 200 mg (as hydrochloride) in 5.3 mL are equivalent for the purposes of substitution.

7246J	Injection	3000 mg	17	..	*274.08	35.40	DBL Gemcitabine Injection (gemcitabine 1 g/26.3 mL injection, 1 x 26.3 mL vial)	HH
							DBL Gemcitabine Injection (gemcitabine 2	HH

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 Name and Manufacturer	
							g/52.6 mL injection, 1 x 52.6 mL vial)	
							DBL Gemcitabine Injection (gemcitabine 200 mg/5.3 mL injection, 1 x 5.3 mL vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 1 g injection, 1 x 1 g vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 2 g injection, 1 x 2 g vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 200 mg injection, 1 x 200 mg vial)	HH
							Gemaccord (gemcitabine 1 g injection, 1 x 1 g vial)	WQ
							Gemaccord (gemcitabine 200 mg injection, 1 x 200 mg vial)	WQ
							Gemcitabine Actavis (gemcitabine 1 g injection, 1 x 1 g vial)	TA
							Gemcitabine Actavis (gemcitabine 200 mg injection, 1 x 200 mg vial)	TA
							Gemcitabine Ebewe (gemcitabine 1 g injection, 1 x 1 g vial)	SZ
							Gemcitabine Ebewe (gemcitabine 1 g/100 mL injection, 1 x 100 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 1 g/25 mL injection, 1 x 25 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 2 g/50 mL injection, 1 x 50 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 200 mg injection, 1 x 200 mg vial)	SZ
							Gemcitabine Ebewe (gemcitabine 200 mg/20 mL injection, 1 x 20 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 200 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 500 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Gemcitabine Kabi (gemcitabine 1 g injection, 1 x 1 g vial)	PK
							Gemcitabine Kabi (gemcitabine 2 g injection, 1 x 2 g vial)	PK
							Gemcitabine Kabi (gemcitabine 200 mg injection, 1 x 200 mg vial)	PK
							Gemcitabine Sun (gemcitabine 1 g injection, 1 x 1 g vial)	ZF
							Gemcitabine Sun (gemcitabine 200 mg injection, 1 x 200 mg vial)	ZF
							Gemplan (gemcitabine 1 g injection, 1 x 1 g vial)	WQ
							Gemplan (gemcitabine 200 mg injection, 1 x 200 mg vial)	WQ
							Gemzar (gemcitabine 1 g injection, 1 x 1 g vial)	LY
							Gemzar (gemcitabine 200 mg injection, 1 x 200 mg vial)	LY

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

VINBLASTINE

7261E	Injection	20 mg	17	..	*137.13	35.40	Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)	HH

VINCRISTINE

7262F	Injection	2 mg	7	..	*104.73	35.40	Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)	HH

VINORELBINE

Authority required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer

Authority required (STREAMLINED)

3907

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 Name and Manufacturer	
	Advanced breast cancer after failure of prior therapy which includes an anthracycline							
7263G	Injection	70 mg	7	..	*227.99	35.40	Hospira Pty Limited (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)	HH
							Hospira Pty Limited (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	HH
							Navelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)	FB
							Navelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	FB
							Vinorelbine Ebewe (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)	SZ
							Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	PK

Podophyllotoxin derivatives

ETOPOSIDE

7237X	Injection	440 mg	14	..	*222.47	35.40	Etopophos (etoposide 1 g injection, 1 x 1 g vial)	BQ
							Etopophos (etoposide 100 mg injection, 1 x 100 mg vial)	BQ
							Etoposide Ebewe (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)	SZ

Taxanes

CABAZITAXEL

Authority required

Castration resistant metastatic carcinoma of the prostate

The Clinical criteria is:

The treatment must be in combination with prednisone or prednisolone,

AND the Clinical criteria is:

Patient must have failed treatment with docetaxel due to resistance or intolerance,

AND the Clinical criteria is:

Patient must have a WHO performance status of 2 or less.

Note

Patients who have received PBS-subsidised cabazitaxel are not eligible for PBS-subsidised docetaxel.

Note

Patients who have progressive disease on cabazitaxel are not eligible to receive PBS-subsidised cabazitaxel.

Note

Special Pricing Arrangements apply.

7236W	Injection	55 mg	5	..	*5961.11	35.40	Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1)	SW

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 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.

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.

7281F	Injection	250 mg	5	..	*978.33	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL	HH

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 Name and Manufacturer	
							vial)	
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HX
							Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HX
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3956

Treatment of HER2 positive 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.

7282G	Injection	250 mg	5	..	*978.33	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	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 Name and Manufacturer	
	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	..	*978.33	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HX
							Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HX
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	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** 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** 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 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	..	*978.33	35.40	DBL Docetaxel Concentrated Injection	HH

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 Name and Manufacturer	
							(docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

4078

Locally advanced or metastatic non-small cell lung cancer

Authority required (STREAMLINED)

4140

Advanced metastatic ovarian cancer

The Clinical criteria is:

Patient must have failed prior therapy which included a platinum compound.

Authority required (STREAMLINED)

4155

Androgen independent (castration resistant) metastatic carcinoma of the prostate

The Clinical criteria is:

Patient must have a Karnofsky performance status score of at least 60%,

AND the Clinical criteria is:

The treatment must be used as first-line chemotherapy,

AND the Clinical criteria is:

The treatment must be administered in three weekly cycles,

AND the Clinical criteria is:

Patient must not receive more than 10 cycles of treatment with docetaxel under this restriction.

Note

Patients who have failed to respond or are intolerant to docetaxel are no longer eligible to receive PBS-subsidised docetaxel.

Note

Patients who have received PBS-subsidised cabazitaxel are not eligible for PBS-subsidised docetaxel.

Authority required (STREAMLINED)

4160

Metastatic breast cancer

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.

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 Name and Manufacturer	
	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	..	*978.33	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HX
							Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HX
							Docetaxel SUN (docetaxel 20 mg injection [1 x 20 mg vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack)	ZF
							Docetaxel SUN (docetaxel 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 x 4 mL vial], 1 pack)	ZF
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW
	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 **Authority required (STREAMLINED)** ***3956*** Treatment of HER2 positive breast cancer in combination with trastuzumab **Authority required (STREAMLINED)** ***3955*** Metastatic breast cancer								
7254T	Injection	450 mg	3	..	*1260.47	35.40	Anzatax (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	HH
							Anzatax (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	HH
							Anzatax (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	HH

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 Name and Manufacturer	
							Anzatax (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	HH
							Paclitaxel Actavis (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	TA
							Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	TA
							Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	TA
							Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	TA
							Paclitaxel Ebewe (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)	SZ
							Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Paclitaxel Kabi (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	PK
							Paclitaxel Kabi (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	PK
							Paclitaxel Kabi (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	PK
							Paclitaxel Pfizer (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	PF
							Paclitaxel Pfizer (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	PF
							Paclitaxel Pfizer (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	PF
							Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	WQ
							Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	WQ
							Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	WQ
							Taxol (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	BQ
							Taxol (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	BQ
							Taxol (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	BQ
	PACLITAXEL NANOPARTICLE ALBUMIN BOUND **Authority required (STREAMLINED)** ***3955*** Metastatic breast cancer **Authority required (STREAMLINED)** ***3956*** Treatment of HER2 positive breast cancer in combination with trastuzumab							
7270P	Injection	580 mg	5	..	*2555.27	35.40	Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial)	TS

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

	DOXORUBICIN							
7229L	Injection/intravesical	135 mg	11	..	*139.52	35.40	Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	WQ
							Adriamycin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	PF
							Adriamycin Solution (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	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 Name and Manufacturer	
							Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Hospira Pty Limited (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	HH
							Hospira Pty Limited (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	HH
	DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL **Authority required** Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen **Authority required** Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane **Authority required** Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated							
7228K	Injection	100 mg	5	..	*3261.32	35.40	Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	JC
7230M	Injection	100 mg	5	..	*3112.97	35.40	Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	JC
							Caelyx (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)	JC
							Lipodox (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	ZF
							Lipodox 50 (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)	ZF
	EPIRUBICIN							
7231N	Injection/intravesical	220 mg	5	..	*248.34	35.40	DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	HH
							Epiccord (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Epiccord (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)	WQ
							Epiccord (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	WQ
							Epiccord (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	WQ
							Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	TA
							Epirubicin Actavis 100 (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	TA
							Epirubicin Actavis 20 (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)	TA
							Epirubicin Actavis 200 (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	TA
							Epirubicin Actavis 50 (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	TA
							Epirubicin Ebewe (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Epirubicin Kabi (epirubicin hydrochloride 200	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 Name and Manufacturer	
							mg/100 mL injection, 1 x 100 mL vial)	
							Epirubicin Kabi (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	PK
							Hospira Pty Limited (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	HH
							Hospira Pty Limited (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	HH
							Pharmorubicin Solution (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	PF
	IDARUBICIN **Restricted benefit** Acute myelogenous leukaemia							
7247K	Injection	30 mg	5	..	*926.00	35.40	Idarubicin Ebewe (idarubicin hydrochloride 10 mg/10 mL injection, 1 x 10 mL vial)	SZ
							Idarubicin Ebewe (idarubicin hydrochloride 5 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6)	PF
							Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3)	PF
	MITOZANTRONE							
7252Q	Injection	30 mg	5	..	*307.75	35.40	Hospira Pty Limited (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	HH
							Mitozantrone Ebewe (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	SZ
							Onkotrone (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	BX
							Onkotrone (mitozantrone 25 mg/12.5 mL injection, 1 x 12.5 mL vial)	BX
							Pfizer Australia Pty Ltd (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	PF
	OTHER ANTINEOPLASTIC AGENTS ***Platinum compounds***							
	CARBOPLATIN							
7222D	Injection	900 mg	5	..	*159.15	35.40	Carboplatin Ebewe (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	SZ
							Carboplatin Ebewe (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	SZ
							Carboplatin Ebewe (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Carboplatin Kabi (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	PK
							Hospira Pty Limited (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	HH
							Hospira Pty Limited (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	HH
							Hospira Pty Limited (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)	HH
							Pfizer Australia Pty Ltd (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	PF
							Pfizer Australia Pty Ltd (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	PF
	CISPLATIN							
7224F	Injection	220 mg	14	..	*118.17	35.40	Cisplatin Ebewe (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Hospira Pty Limited (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)	HH
							Hospira Pty Limited (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)	HH
							Pfizer Australia Pty Ltd (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)	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 Name and Manufacturer	
							Pfizer Australia Pty Ltd (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)	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.								
7253R	Injection	300 mg	11	..	*328.25	35.40	DBL Oxaliplatin Concentrate (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	HH
							DBL Oxaliplatin Concentrate (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	HH
							Eloxatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	SW
							Eloxatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)	SW
							Eloxatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	SW
							Hospira Pty Limited (oxaliplatin 100 mg injection, 1 x 100 mg vial)	HH
							Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial)	HH
							Oxaliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	WQ
							Oxaliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	WQ
							Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial)	TA
							Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial)	TA
							Oxaliplatin Alphapharm (oxaliplatin 100 mg injection, 1 x 100 mg vial)	AF
							Oxaliplatin Alphapharm (oxaliplatin 50 mg injection, 1 x 50 mg vial)	AF
							Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial)	SZ
							Oxaliplatin Ebewe (oxaliplatin 50 mg injection, 1 x 50 mg vial)	SZ
							Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	PK
							Oxaliplatin Kabi (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	PK
							Oxaliplatin SUN (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	ZF
							Oxaliplatin SUN (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)	ZF

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 Name and Manufacturer	
							Oxaliplatin SUN (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	ZF
							Xalox (oxaliplatin 100 mg injection, 1 x 100 mg vial)	WQ
							Xalox (oxaliplatin 50 mg injection, 1 x 50 mg vial)	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.

The maximum dose that will be approved is 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks

Authority required

Continuing PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with metastatic colorectal cancer who has previously been issued with an authority prescription for bevacizumab and who does not have progressive disease and who remains on first-line chemotherapy.

The maximum dose that will be approved is 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks

Note

Special Pricing Arrangements apply.

Note

Not for use as monotherapy.

7243F	Injection	900 mg	11	..	*4000.81	35.40	Avastin (bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial)	RO
							Avastin (bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial)	RO

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

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	..	..	*3211.49	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

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	..	*2169.04	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

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.

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 Name and Manufacturer	
	Note Special Pricing Arrangements apply.							
7242E	Injection	880 mg	..	..	*3211.49	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial) Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG SG
	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	..	*2169.04	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial) Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG SG
	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	..	*3759.35	35.40	Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)	RO RO
	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	..	*3759.35	35.40	Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)	RO RO
	RITUXIMAB **Authority required** CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide **Note** Rituximab is not PBS-subsidised for use as monotherapy.							
7259C	Injection	1100 mg	5	..	*5109.25	35.40	Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)	RO RO
	TRASTUZUMAB **Authority required** Locally advanced HER2 positive breast cancer Treatment Phase: Initial treatment (weekly regimen) **The Clinical criteria is:** Patient must commence treatment concurrently with neoadjuvant chemotherapy,							

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 Name and Manufacturer	
	AND the Clinical criteria is: The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND the Clinical criteria is:** Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes: (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and (ii) a copy of the signed patient acknowledgement form. 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. 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. **Authority required** Early HER2 positive breast cancer Treatment Phase: Initial treatment (weekly regimen) **The Clinical criteria is:** Patient must commence treatment concurrently with adjuvant chemotherapy, **AND the Clinical criteria is:** Patient must have undergone surgery, **AND the Clinical criteria is:** The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND the Clinical criteria is:** Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes: (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and (ii) a copy of the signed patient acknowledgement form. 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. 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. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
7264H	Injection	500 mg	..	..	*3613.52	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO RO

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 Name and Manufacturer	
	TRASTUZUMAB **Authority required** Locally advanced HER2 positive breast cancer Treatment Phase: Continuing treatment (weekly regimen) **The Clinical criteria is:** Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND the Clinical criteria is:** The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND the Clinical criteria is:** Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment. 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. 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 required** Early HER2 positive breast cancer Treatment Phase: Continuing treatment (weekly regimen) **The Clinical criteria is:** Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND the Clinical criteria is:** The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND the Clinical criteria is:** Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment. 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. 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. **Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Note** Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
7265J	Injection	250 mg	9	..	*1966.74	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO RO
	TRASTUZUMAB **Authority required**							

Chemotherapy Items for Private Hospital/Private Clinic use

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Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

The Clinical criteria is:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

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.

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.

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

The Clinical criteria is:

Patient must commence treatment concurrently with adjuvant chemotherapy,

AND the Clinical criteria is:

Patient must have undergone surgery,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

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.

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.

Note

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

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 Name and Manufacturer	
	HOBART TAS 7001							
7266K	Injection	1000 mg	..	..	*7120.75	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO RO

TRASTUZUMAB

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

The Clinical criteria is:

Patient must have previously received treatment with PBS-subsidised trastuzumab,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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.

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 required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

The Clinical criteria is:

Patient must have previously received treatment with PBS-subsidised trastuzumab,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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.

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.

Note

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

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

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HOBART TAS 7001

7267L	Injection	750 mg	3	..	*5266.18	35.40	Herceptin (trastuzumab 150 mg injection, 1 x	RO

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 Name and Manufacturer	
							150 mg vial)	
							Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO

Other antineoplastic agents

ARSENIC

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	..	*910.09	35.40	Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)	PL

BORTEZOMIB

Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

The Clinical criteria is:

Patient must be newly diagnosed,

AND the Clinical criteria is:

Patient must be ineligible for high dose chemotherapy,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma and ineligibility for high dose chemotherapy; and

(3) a signed patient acknowledgement.

Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

The Clinical criteria is:

Patient must be newly diagnosed,

AND the Clinical criteria is:

Patient must have severe acute renal failure,

AND the Clinical criteria is:

Patient must require dialysis; OR

Patient must be at high risk of requiring dialysis in the opinion of a nephrologist,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response; and

(3) a signed patient acknowledgement.

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 Name and Manufacturer	
	Disease activity parameters include current diagnostic reports of at least one of the following: (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) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. **Note** Patients who have initiated treatment with thalidomide within the last month do not have to experience failure after a trial of at least 4 weeks of thalidomide or to have failed to achieve at least a minimal response after at least 8 weeks of thalidomide treatment. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 **Note** Special Pricing Arrangements apply.							
7238Y	Injection	3000 mcg	31	..	*1604.27	35.40	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC

BORTEZOMIB

Authority required

Multiple myeloma

Treatment Phase: Treatment of Progressive disease - Initial PBS-subsidised treatment

The Clinical criteria is:

The condition must be confirmed by a histological diagnosis,

AND the Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have progressive disease after at least one prior therapy,

AND the Clinical criteria is:

Patient must have undergone or be ineligible for a primary stem cell transplant,

AND the Clinical criteria is:

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,

AND the Clinical criteria is:

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND the Clinical criteria is:

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 Name and Manufacturer

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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.

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 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

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.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Authority required

Multiple myeloma

Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have previously received 4 treatment cycles of bortezomib for progressive disease,

AND the Clinical criteria is:

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 Name and Manufacturer	
	Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib,							
	AND the Clinical criteria is:							
	Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,							
	AND the Clinical criteria is:							
	Patient must not have a gap of more than 6 months between the initial application and subsequent applications,							
	AND the Clinical criteria is:							
	Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.							
	The authority application must be made in writing and must include:							
	(1) a completed authority prescription form; and							
	(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and							
	(3) diagnostic reports demonstrating the patient has achieved at least a partial response.							
	If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).							
	If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:							
	(a) at least a 50% reduction in bone marrow plasma cells; or							
	(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or							
	(c) 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							
	(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.							
	Diagnostic reports must be no more than one month old at the time of application.							
	Where a response assessment is not submitted prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib.							
	Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.							
	Note 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.							
	Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
	Applications for authority to prescribe should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	Note Special Pricing Arrangements apply.							
7268M	Injection	3000 mcg	15	..	*1858.93	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC
	BORTEZOMIB **Authority required** Multiple myeloma							
	Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment							
	The Clinical criteria is:							
	The treatment must be as monotherapy; OR							
	The treatment must be in combination with a corticosteroid and/or 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 Name and Manufacturer	
	AND the Clinical criteria is: Patient must have previously received 8 treatment cycles of bortezomib for progressive disease, **AND the Clinical criteria is:** Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib, **AND the Clinical criteria is:** Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, **AND the Clinical criteria is:** Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles, **AND the Clinical criteria is:** Patient must not receive more than 3 cycles of bortezomib under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and (3) diagnostic reports demonstrating the patient has achieved at least a partial response. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) 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 (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Diagnostic reports must be no more than one month old at the time of application. Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 **Note** Special Pricing Arrangements apply.							
7269N	Injection	3000 mcg	11	..	*1858.93	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC

BORTEZOMIB

Authority required

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Initial PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

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The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have progressive disease,

AND the Clinical criteria is:

Patient must have previously been treated with PBS-subsidised bortezomib,

AND the Clinical criteria is:

Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy,

AND the Clinical criteria is:

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) 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

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib 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; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(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,

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evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Authority required

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Continuing PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have previously received 4 treatment cycles of bortezomib in the current treatment course,

AND the Clinical criteria is:

Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib,

AND the Clinical criteria is:

Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,

AND the Clinical criteria is:

Patient must not have a gap of more than 6 months between the initial application and subsequent applications,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) 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

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Diagnostic reports must be no more than one month old at the time of application.

Where a response assessment is not submitted prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib.

Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.

Note

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.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

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Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Special Pricing Arrangements apply.							
7271Q	Injection	3000 mcg	15	..	*1858.93	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC

BORTEZOMIB

Authority required

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Continuing PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have previously received 8 treatment cycles of bortezomib in the current treatment course,

AND the Clinical criteria is:

Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib,

AND the Clinical criteria is:

Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,

AND the Clinical criteria is:

Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles,

AND the Clinical criteria is:

Patient must not receive more than 3 cycles of bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) 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

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Diagnostic reports must be no more than one month old at the time of application.

Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib.

Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

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HOBART TAS 7001

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Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Note Special Pricing Arrangements apply.							
7272R	Injection	3000 mcg	11	..	*1858.93	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC

BORTEZOMIB

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

The Clinical criteria is:

Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and be ineligible for high dose chemotherapy,

AND the Clinical criteria is:

Patient must not have demonstrated progressive disease at the time of application,

AND the Clinical criteria is:

Patient must not have achieved a best confirmed response to bortezomib at the time of application,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide,

AND the Clinical criteria is:

Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application.

Note

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

The Clinical criteria is:

Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and have severe acute renal failure,

AND the Clinical criteria is:

Patient must have demonstrated at least a partial response at the completion of cycle 4 at the time of application,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form, which includes a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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 not being used to monitor disease activity, partial response compared with

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	baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) 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 (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 **Note** Authority applications for continuing treatment may be faxed to the Department of Human Services on 1300 154 190 (hours of operation 8.a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone. **Note** Special Pricing Arrangements apply.							
7274W	Injection	3000 mcg	19	..	*1604.27	35.40	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
	BORTEZOMIB **Authority required** Symptomatic multiple myeloma **The Clinical criteria is:** Patient must be newly diagnosed, **AND the Clinical criteria is:** Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation, **AND the Clinical criteria is:** Patient must not be receiving PBS-subsidised thalidomide or lenalidomide, **AND the Clinical criteria is:** The treatment must be in combination with chemotherapy, **AND the Clinical criteria is:** Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma; and (3) a signed patient acknowledgement. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826							

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 Name and Manufacturer	
	GPO Box 9826 HOBART TAS 7001							
	Note Special Pricing Arrangements apply.							
7275X	Injection	3000 mcg	15	..	*1604.27	35.40	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
	IRINOTECAN **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	..	*396.25	35.40	Camptosar (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)	PF
							Hospira Pty Limited (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	HH
							Hospira Pty Limited (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	HH
							Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	HH
							Irinoccord (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Irinoccord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	WQ
							Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	TA
							Irinotecan Actavis (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	TA
							Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	TA
							Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	AF
							Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	AF
							Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	AF
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)	SZ
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Irinotecan Kabi (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	PK
							Irinotecan Kabi (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	PK
							Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL	OE

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Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							injection, 1 x 5 mL vial)	
							Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	OE
							Tecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	WQ
							Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	WQ
	TOPOTECAN **Authority required (STREAMLINED)** ***3186*** Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound							
7260D	Injection	3500 mcg	17	..	*424.77	35.40	Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials)	GK
							Topotecan Kabi (topotecan 4 mg injection, 5 x 4 mg vials)	PK

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 32.

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Total Dispensed Price for Max. Amount $	Proposed Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
# 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 iu	11	$61.78	*109.34	*171.12	35.40	Bleo 15K (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial) Hospira Pty Limited (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial)	WQ HH

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

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

CYCLOPHOSPHAMIDE

4327R	Injection	2800 mg	17	..	*104.27	35.40	Endoxan (cyclophosphamide 1 g injection, 1 x 1 g vial)	BX
							Endoxan (cyclophosphamide 2 g injection, 1 x 2 g vial)	BX
							Endoxan (cyclophosphamide 500 mg injection, 1 x 500 mg vial)	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	..	*277.24	35.40	Holoxan (ifosfamide 1 g injection, 1 x 1 g vial)	BX
							Holoxan (ifosfamide 2 g injection, 1 x 2 g vial)	BX

Nitrosoureas

FOTEMUSTINE
Authority required (STREAMLINED)
3181
Metastatic malignant melanoma

4437M	Injection	220 mg	8	..	*2209.30	35.40	Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&) inert substance diluent [1 x 4 mL ampoule], 1 pack)	SE

ANTIMETABOLITES

Folic acid analogues

METHOTREXATE

4502Y	Injection	250 mg	5	..	*59.44	35.40	Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	HH
							Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)	HH
							Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)	HH
							Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)	HH
							Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)	WQ
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	WQ
							Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)	PF

METHOTREXATE
Restricted benefit
Patients receiving treatment with a high dose regimen.

4512L	Injection	20000 mg	..	..	*1544.24	35.40	Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	HH
							Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)	HH
							Hospira Pty Limited (methotrexate 50 mg/2 mL	HH

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							injection, 5 x 2 mL vials)	
							Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)	HH
							Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)	WQ
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	WQ
							Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)	PF
	PEMETREXED **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							
4600D	Injection	1100 mg	5	..	*3472.31	35.40	Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial)	LY
							Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial)	LY
	RALTITREXED **Authority required (STREAMLINED)** ***3185*** For use as a single agent in the treatment of advanced colorectal cancer							
4610P	Injection	7 mg	8	..	*1054.00	35.40	Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial)	HH
	Purine analogues							
	CLADRIBINE **Authority required (STREAMLINED)** ***3180*** Hairy cell leukaemia							
4326Q	Injection	17 mg	6	..	*1321.56	35.40	Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial)	JC
							Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial)	OA
	FLUDARABINE **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 5,000 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	..	*589.12	35.40	Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	WQ

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)	GZ
							Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	TA
							Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)	SZ
	Pyrimidine analogues							
	CYTARABINE							
4357H	Injection	7000 mg	15	..	*746.94	35.40	Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)	PF
	FLUOROURACIL **Restricted benefit** For patients requiring administration of fluorouracil by intravenous infusion.							
4394G	Injection	5500 mg	11	..	*78.81	35.40	DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)	HH
							DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	HH
							Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH
	FLUOROURACIL **Restricted benefit** For patients requiring administration of fluorouracil by intravenous injection.							
4431F	Injection	1000 mg	23	..	*47.58	35.40	DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)	HH
							DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	HH
							Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)	SZ
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH
	GEMCITABINE **Caution** Pharmaceutical benefits containing gemcitabine may have different concentrations. **Note** Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL, gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL and gemcitabine solution for injection 200 mg (as hydrochloride) in 5.3 mL are equivalent for the purposes of substitution. **Note** Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL, gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL and gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution. **Note** Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL and gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.							
4439P	Injection	3000 mg	17	..	*223.07	35.40	DBL Gemcitabine Injection (gemcitabine 1	HH

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							g/26.3 mL injection, 1 x 26.3 mL vial)	
							DBL Gemcitabine Injection (gemcitabine 2 g/52.6 mL injection, 1 x 52.6 mL vial)	HH
							DBL Gemcitabine Injection (gemcitabine 200 mg/5.3 mL injection, 1 x 5.3 mL vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 1 g injection, 1 x 1 g vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 2 g injection, 1 x 2 g vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 200 mg injection, 1 x 200 mg vial)	HH
							Gemaccord (gemcitabine 1 g injection, 1 x 1 g vial)	WQ
							Gemaccord (gemcitabine 200 mg injection, 1 x 200 mg vial)	WQ
							Gemcitabine Actavis (gemcitabine 1 g injection, 1 x 1 g vial)	TA
							Gemcitabine Actavis (gemcitabine 200 mg injection, 1 x 200 mg vial)	TA
							Gemcitabine Ebewe (gemcitabine 1 g injection, 1 x 1 g vial)	SZ
							Gemcitabine Ebewe (gemcitabine 1 g/100 mL injection, 1 x 100 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 1 g/25 mL injection, 1 x 25 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 2 g/50 mL injection, 1 x 50 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 200 mg injection, 1 x 200 mg vial)	SZ
							Gemcitabine Ebewe (gemcitabine 200 mg/20 mL injection, 1 x 20 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 200 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Gemcitabine Ebewe (gemcitabine 500 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Gemcitabine Kabi (gemcitabine 1 g injection, 1 x 1 g vial)	PK
							Gemcitabine Kabi (gemcitabine 2 g injection, 1 x 2 g vial)	PK
							Gemcitabine Kabi (gemcitabine 200 mg injection, 1 x 200 mg vial)	PK
							Gemcitabine Sun (gemcitabine 1 g injection, 1 x 1 g vial)	ZF
							Gemcitabine Sun (gemcitabine 200 mg injection, 1 x 200 mg vial)	ZF
							Gemplan (gemcitabine 1 g injection, 1 x 1 g vial)	WQ
							Gemplan (gemcitabine 200 mg injection, 1 x 200 mg vial)	WQ
							Gemzar (gemcitabine 1 g injection, 1 x 1 g vial)	LY
							Gemzar (gemcitabine 200 mg injection, 1 x 200 mg vial)	LY

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

VINBLASTINE

4618C	Injection	20 mg	17	..	*95.88	35.40	Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)	HH

VINCRISTINE

4619D	Injection	2 mg	7	..	*65.30	35.40	Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)	HH

VINORELBINE

Authority required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer

Authority required (STREAMLINED)

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	3907							
	Advanced breast cancer after failure of prior therapy which includes an anthracycline							
4620E	Injection	70 mg	7	..	*178.78	35.40	Hospira Pty Limited (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)	HH
							Hospira Pty Limited (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	HH
							Navelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)	FB
							Navelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	FB
							Vinorelbine Ebewe (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)	SZ
							Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	PK

Podophyllotoxin derivatives

ETOPOSIDE

4428C	Injection	440 mg	14	..	*173.44	35.40	Etopophos (etoposide 1 g injection, 1 x 1 g vial)	BQ
							Etopophos (etoposide 100 mg injection, 1 x 100 mg vial)	BQ
							Etoposide Ebewe (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)	SZ

Taxanes

CABAZITAXEL

Authority required (STREAMLINED)

4138

Castration resistant metastatic carcinoma of the prostate

The Clinical criteria is:

The treatment must be in combination with prednisone or prednisolone,

AND the Clinical criteria is:

Patient must have failed treatment with docetaxel due to resistance or intolerance,

AND the Clinical criteria is:

Patient must have a WHO performance status of 2 or less.

Note

Patients who have received PBS-subsidised cabazitaxel are not eligible for PBS-subsidised docetaxel.

Note

Patients who have progressive disease on cabazitaxel are not eligible to receive PBS-subsidised cabazitaxel.

Note

Special Pricing Arrangements apply.

4376H	Injection	55 mg	5	..	*5855.38	35.40	Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1)	SW

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	..	*907.92	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HX
							Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HX
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3956

Treatment of HER2 positive 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	..	*907.92	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4	SW

Chemotherapy Items for Public Hospital

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

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

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

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 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	..	*907.92	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HX
							Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HX
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	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

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

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 80 mg in 4 mL and pharmaceutical benefits that have the

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	form docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.							
5584X	Injection	250 mg	5	..	*907.92	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

4078

Locally advanced or metastatic non-small cell lung cancer

Authority required (STREAMLINED)

4140

Advanced metastatic ovarian cancer

The Clinical criteria is:

Patient must have failed prior therapy which included a platinum compound.

Authority required (STREAMLINED)

4155

Androgen independent (castration resistant) metastatic carcinoma of the prostate

The Clinical criteria is:

Patient must have a Karnofsky performance status score of at least 60%,

AND the Clinical criteria is:

The treatment must be used as first-line chemotherapy,

AND the Clinical criteria is:

The treatment must be administered in three weekly cycles,

AND the Clinical criteria is:

Patient must not receive more than 10 cycles of treatment with docetaxel under this restriction.

Note

Patients who have failed to respond or are intolerant to docetaxel are no longer eligible to receive PBS-subsidised docetaxel.

Note

Patients who have received PBS-subsidised cabazitaxel are not eligible for PBS-subsidised docetaxel.

Authority required (STREAMLINED)

4160

Metastatic breast cancer

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

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	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.							
	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	..	*907.92	35.40	DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HH
							DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HH
							Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	HX
							Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	HX
							Docetaxel SUN (docetaxel 20 mg injection [1 x 20 mg vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack)	ZF
							Docetaxel SUN (docetaxel 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 x 4 mL vial], 1 pack)	ZF
							Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	TA
							Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	TA
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	TA
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW
	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 **Authority required (STREAMLINED)** ***3956*** Treatment of HER2 positive breast cancer in combination with trastuzumab **Authority required (STREAMLINED)** ***3955*** Metastatic breast cancer								
4567J	Injection	450 mg	3	..	*1179.20	35.40	Anzatax (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	HH
							Anzatax (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	HH

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							Anzatax (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	HH
							Anzatax (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	HH
							Paclitaxel Actavis (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	TA
							Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	TA
							Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	TA
							Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	TA
							Paclitaxel Ebewe (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)	SZ
							Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Paclitaxel Kabi (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	PK
							Paclitaxel Kabi (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	PK
							Paclitaxel Kabi (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	PK
							Paclitaxel Pfizer (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	PF
							Paclitaxel Pfizer (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	PF
							Paclitaxel Pfizer (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	PF
							Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	WQ
							Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	WQ
							Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	WQ
							Taxol (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	BQ
							Taxol (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	BQ
							Taxol (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	BQ
	PACLITAXEL NANOPARTICLE ALBUMIN BOUND **Authority required (STREAMLINED)** ***3955*** Metastatic breast cancer **Authority required (STREAMLINED)** ***3956*** Treatment of HER2 positive breast cancer in combination with trastuzumab							
4531L	Injection	580 mg	5	..	*2449.52	35.40	Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial)	TS

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

	DOXORUBICIN							
4361M	Injection/intravesical	135 mg	11	..	*98.05	35.40	Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	WQ
							Adriamycin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	PF
							Adriamycin Solution (doxorubicin	PF

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	
							Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Hospira Pty Limited (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	HH
							Hospira Pty Limited (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	HH
	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								
4360L	Injection	100 mg	5	..	*3155.59	35.40	Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	JC
4364Q	Injection	100 mg	5	..	*3007.24	35.40	Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	JC
							Caelyx (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)	JC
							Lipodox (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	ZF
							Lipodox 50 (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)	ZF
	EPIRUBICIN							
4375G	Injection/intravesical	220 mg	5	..	*202.09	35.40	DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	HH
							Epiccord (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Epiccord (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)	WQ
							Epiccord (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	WQ
							Epiccord (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	WQ
							Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	TA
							Epirubicin Actavis 100 (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	TA
							Epirubicin Actavis 20 (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)	TA
							Epirubicin Actavis 200 (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	TA
							Epirubicin Actavis 50 (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	TA
							Epirubicin Ebewe (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							Epirubicin Ebewe (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Epirubicin Kabi (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	PK
							Epirubicin Kabi (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	PK
							Hospira Pty Limited (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	HH
							Hospira Pty Limited (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	HH
							Pharmorubicin Solution (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	PF
	IDARUBICIN							
	Restricted benefit							
	Acute myelogenous leukaemia							
4440Q	Injection	30 mg	5	..	*857.60	35.40	Idarubicin Ebewe (idarubicin hydrochloride 10 mg/10 mL injection, 1 x 10 mL vial)	SZ
							Idarubicin Ebewe (idarubicin hydrochloride 5 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6)	PF
							Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3)	PF
	MITOZANTRONE							
4514N	Injection	30 mg	5	..	*254.02	35.40	Hospira Pty Limited (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	HH
							Mitozantrone Ebewe (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	SZ
							Onkotrone (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	BX
							Onkotrone (mitozantrone 25 mg/12.5 mL injection, 1 x 12.5 mL vial)	BX
							Pfizer Australia Pty Ltd (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)	PF
	OTHER ANTINEOPLASTIC AGENTS							
	Platinum compounds							
	CARBOPLATIN							
4309T	Injection	900 mg	5	..	*115.90	35.40	Carboplatin Ebewe (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	SZ
							Carboplatin Ebewe (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	SZ
							Carboplatin Ebewe (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Carboplatin Kabi (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	PK
							Hospira Pty Limited (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	HH
							Hospira Pty Limited (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	HH
							Hospira Pty Limited (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)	HH
							Pfizer Australia Pty Ltd (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	PF
							Pfizer Australia Pty Ltd (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)	PF
	CISPLATIN							
4319H	Injection	220 mg	14	..	*77.94	35.40	Cisplatin Ebewe (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)	SZ

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							Hospira Pty Limited (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)	HH
							Hospira Pty Limited (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)	HH
							Pfizer Australia Pty Ltd (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)	PF
							Pfizer Australia Pty Ltd (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)	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** 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. **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** 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.								
4542C	Injection	300 mg	11	..	*277.52	35.40	DBL Oxaliplatin Concentrate (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	HH
							DBL Oxaliplatin Concentrate (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	HH
							Eloxatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	SW
							Eloxatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)	SW
							Eloxatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	SW
							Hospira Pty Limited (oxaliplatin 100 mg injection, 1 x 100 mg vial)	HH
							Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial)	HH
							Oxaliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	WQ
							Oxaliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	WQ
							Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial)	TA
							Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial)	TA
							Oxaliplatin Alphapharm (oxaliplatin 100 mg injection, 1 x 100 mg vial)	AF
							Oxaliplatin Alphapharm (oxaliplatin 50 mg injection, 1 x 50 mg vial)	AF
							Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial)	SZ
							Oxaliplatin Ebewe (oxaliplatin 50 mg injection, 1 x 50 mg vial)	SZ
							Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	PK

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							Oxaliplatin Kabi (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	PK
							Oxaliplatin SUN (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	ZF
							Oxaliplatin SUN (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)	ZF
							Oxaliplatin SUN (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	ZF
							Xalox (oxaliplatin 100 mg injection, 1 x 100 mg vial)	WQ
							Xalox (oxaliplatin 50 mg injection, 1 x 50 mg vial)	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.

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

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

Special Pricing Arrangements apply.

Note

Not for use as monotherapy.

4400N	Injection	900 mg	11	..	*3910.64	35.40	Avastin (bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial)	RO
							Avastin (bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial)	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

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	..	..	*3109.64	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	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	..	*2086.64	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x	SG

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							20 mL vial)	
							Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	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.

4436L	Injection	880 mg	..	..	*3109.64	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	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

Special Pricing Arrangements apply.

Note

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

4731B	Injection	550 mg	11	..	*2086.64	35.40	Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

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	..	*3662.37	35.40	Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)	RO
							Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)	RO

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	..	*3662.37	35.40	Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)	RO
							Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)	RO

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	RITUXIMAB							
	Authority required (STREAMLINED)							
	3932							
	CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide							
	Note							
	Rituximab is not PBS-subsidised for use as monotherapy.							
4615X	Injection	1100 mg	5	..	*5020.50	35.40	Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)	RO
							Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)	RO
	TRASTUZUMAB							
	Authority required							
	Locally advanced HER2 positive breast cancer							
	Treatment Phase: Initial treatment (weekly regimen)							
	The Clinical criteria is:							
	Patient must commence treatment concurrently with neoadjuvant chemotherapy,							
	AND the Clinical criteria is:							
	The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,							
	AND the Clinical criteria is:							
	Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.							
	HER2 positivity must be demonstrated by in situ hybridisation (ISH).							
	Authority applications for initial treatment must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:							
	(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and							
	(ii) a copy of the signed patient acknowledgement form.							
	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.							
	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.							
	Authority required							
	Early HER2 positive breast cancer							
	Treatment Phase: Initial treatment (weekly regimen)							
	The Clinical criteria is:							
	Patient must commence treatment concurrently with adjuvant chemotherapy,							
	AND the Clinical criteria is:							
	Patient must have undergone surgery,							
	AND the Clinical criteria is:							
	The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,							
	AND the Clinical criteria is:							
	Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.							
	HER2 positivity must be demonstrated by in situ hybridisation (ISH).							
	Authority applications for initial treatment must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:							
	(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and							
	(ii) a copy of the signed patient acknowledgement form.							
	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.							
	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							

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	single loading dose of 4 mg per kg.							
	Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
4632T	Injection	500 mg	..	..	*3543.33	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO RO

TRASTUZUMAB

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

The Clinical criteria is:

Patient must have previously received treatment with PBS-subsidised trastuzumab,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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.

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 required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

The Clinical criteria is:

Patient must have previously received treatment with PBS-subsidised trastuzumab,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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.

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.

Note

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
	Applications for authority to prescribe should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
4639E	Injection	250 mg	9	..	*1895.01	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial)	RO
							Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO

TRASTUZUMAB

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

The Clinical criteria is:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

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.

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.

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

The Clinical criteria is:

Patient must commence treatment concurrently with adjuvant chemotherapy,

AND the Clinical criteria is:

Patient must have undergone surgery,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	(ISH); and (ii) a copy of the signed patient acknowledgement form. 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. 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. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
4650R	Injection	1000 mg	..	..	*7046.00	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO RO

TRASTUZUMAB

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

The Clinical criteria is:

Patient must have previously received treatment with PBS-subsidised trastuzumab,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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.

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 required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

The Clinical criteria is:

Patient must have previously received treatment with PBS-subsidised trastuzumab,

AND the Clinical criteria is:

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,

AND the Clinical criteria is:

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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.

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.

Note

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Note Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
4703M	Injection	750 mg	3	..	*5191.65	35.40	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial)	RO
							Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)	RO

Other antineoplastic agents

ARSENIC
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

Code								
4371C	Injection	18 mg	89	..	*842.30	35.40	Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)	PL

BORTEZOMIB
Authority required
Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

The Clinical criteria is:

Patient must be newly diagnosed,

AND the Clinical criteria is:

Patient must be ineligible for high dose chemotherapy,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma and ineligibility for high dose chemotherapy; and

(3) a signed patient acknowledgement.

Authority required
Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

The Clinical criteria is:

Patient must be newly diagnosed,

AND the Clinical criteria is:

Patient must have severe acute renal failure,

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	AND the Clinical criteria is: Patient must require dialysis; OR Patient must be at high risk of requiring dialysis in the opinion of a nephrologist, **AND the Clinical criteria is:** The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND the Clinical criteria is:** Patient must not be receiving PBS-subsidised thalidomide or lenalidomide, **AND the Clinical criteria is:** Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response; and (3) a signed patient acknowledgement. Disease activity parameters include current diagnostic reports of at least one of the following: (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) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. **Note** Patients who have initiated treatment with thalidomide within the last month do not have to experience failure after a trial of at least 4 weeks of thalidomide or to have failed to achieve at least a minimal response after at least 8 weeks of thalidomide treatment. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 **Note** Special Pricing Arrangements apply.							
4403R	Injection	3000 mcg	31	..	*1509.77	35.40	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC

BORTEZOMIB

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Chemotherapy Items for Public Hospital

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

The Clinical criteria is:

Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and be ineligible for high dose chemotherapy,

AND the Clinical criteria is:

Patient must not have demonstrated progressive disease at the time of application,

AND the Clinical criteria is:

Patient must not have achieved a best confirmed response to bortezomib at the time of application,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide,

AND the Clinical criteria is:

Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application.

Note

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

The Clinical criteria is:

Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and have severe acute renal failure,

AND the Clinical criteria is:

Patient must have demonstrated at least a partial response at the completion of cycle 4 at the time of application,

AND the Clinical criteria is:

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,

AND the Clinical criteria is:

Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form, which includes a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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 not being used to monitor disease activity, partial response compared with baseline is defined as:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) 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

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application.

Note

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

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Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 **Note** Authority applications for continuing treatment may be faxed to the Department of Human Services on 1300 154 190 (hours of operation 8.a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone. **Note** Special Pricing Arrangements apply.							
4429D	Injection	3000 mcg	19	..	*1509.77	35.40	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC

BORTEZOMIB

Authority required

Multiple myeloma

Treatment Phase: Treatment of Progressive disease - Initial PBS-subsidised treatment

The Clinical criteria is:

The condition must be confirmed by a histological diagnosis,

AND the Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have progressive disease after at least one prior therapy,

AND the Clinical criteria is:

Patient must have undergone or be ineligible for a primary stem cell transplant,

AND the Clinical criteria is:

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,

AND the Clinical criteria is:

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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.

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.

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

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

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.

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

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Authority required

Multiple myeloma

Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have previously received 4 treatment cycles of bortezomib for progressive disease,

AND the Clinical criteria is:

Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib,

AND the Clinical criteria is:

Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,

AND the Clinical criteria is:

Patient must not have a gap of more than 6 months between the initial application and subsequent applications,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at

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	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: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) 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 (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Diagnostic reports must be no more than one month old at the time of application. Where a response assessment is not submitted prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart. **Note** 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. **Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 **Note** Special Pricing Arrangements apply.							
4706Q	Injection	3000 mcg	15	..	*1754.64	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC

BORTEZOMIB

Authority required

Multiple myeloma

Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have previously received 8 treatment cycles of bortezomib for progressive disease,

AND the Clinical criteria is:

Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib,

AND the Clinical criteria is:

Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,

AND the Clinical criteria is:

Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles,

AND the Clinical criteria is:

Patient must not receive more than 3 cycles of bortezomib under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50%

Chemotherapy Items for Public Hospital

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reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) 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

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Diagnostic reports must be no more than one month old at the time of application.

Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib.

Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

4712B	Injection	3000 mcg	11	..	*1754.64	35.40	Velcade (bortezomib 3.5 mg injection, 1 x3.51 mg vial)	JC

BORTEZOMIB

Authority required

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Initial PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have progressive disease,

AND the Clinical criteria is:

Patient must have previously been treated with PBS-subsidised bortezomib,

AND the Clinical criteria is:

Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy,

AND the Clinical criteria is:

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND the Clinical criteria is:

Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

Chemotherapy Items for Public Hospital

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

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.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) 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

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib 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; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

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

Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Authority required

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Continuing PBS-subsidised treatment

The Clinical criteria is:

The treatment must be as monotherapy; OR

The treatment must be in combination with a corticosteroid and/or cyclophosphamide,

AND the Clinical criteria is:

Patient must have previously received 4 treatment cycles of bortezomib in the current treatment course,

AND the Clinical criteria is:

Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib,

AND the Clinical criteria is:

Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,

AND the Clinical criteria is:

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Patient must not have a gap of more than 6 months between the initial application and subsequent applications,							
	AND the Clinical criteria is:							
	Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.							
	The authority application must be made in writing and must include:							
	(1) a completed authority prescription form; and							
	(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and							
	(3) diagnostic reports demonstrating the patient has achieved at least a partial response.							
	If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).							
	If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:							
	(a) at least a 50% reduction in bone marrow plasma cells; or							
	(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or							
	(c) 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							
	(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.							
	Diagnostic reports must be no more than one month old at the time of application.							
	Where a response assessment is not submitted prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib.							
	Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.							
	Note 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.							
	Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
	Applications for authority to prescribe should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	Note Special Pricing Arrangements apply.							
4713C	Injection	3000 mcg	15	..	*1754.64	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC
	BORTEZOMIB **Authority required** Multiple myeloma							
	Treatment Phase: Retreatment of Progressive disease - Continuing PBS-subsidised treatment							
	The Clinical criteria is:							
	The treatment must be as monotherapy; OR							
	The treatment must be in combination with a corticosteroid and/or cyclophosphamide,							
	AND the Clinical criteria is:							
	Patient must have previously received 8 treatment cycles of bortezomib in the current treatment course,							
	AND the Clinical criteria is:							
	Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib,							

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	AND the Clinical criteria is:							
	Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,							
	AND the Clinical criteria is:							
	Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles,							
	AND the Clinical criteria is:							
	Patient must not receive more than 3 cycles of bortezomib under this restriction.							
	The authority application must be made in writing and must include:							
	(1) a completed authority prescription form; and							
	(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and							
	(3) diagnostic reports demonstrating the patient has achieved at least a partial response.							
	If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).							
	If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as 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 is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as 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:							
	(a) at least a 50% reduction in bone marrow plasma cells; or							
	(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or							
	(c) 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							
	(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.							
	Diagnostic reports must be no more than one month old at the time of application.							
	Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib.							
	Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.							
	Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
	Applications for authority to prescribe should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	Note Special Pricing Arrangements apply.							
4725Q	Injection	3000 mcg	11	..	*1754.64	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC
	BORTEZOMIB **Authority required** Symptomatic multiple myeloma							
	The Clinical criteria is:							
	Patient must be newly diagnosed,							
	AND the Clinical criteria is:							
	Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation,							
	AND the Clinical criteria is:							
	Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,							
	AND the Clinical criteria is:							

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	The treatment must be in combination with chemotherapy,							
	AND the Clinical criteria is:							
	Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.							
	The authority application must be made in writing and must include:							
	(1) a completed authority prescription form; and							
	(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma; and							
	(3) a signed patient acknowledgement.							
	Note							
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
	Applications for authority to prescribe should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	Note							
	Special Pricing Arrangements apply.							
4732C	Injection	3000 mcg	15	..	*1509.77	35.40	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC
	IRINOTECAN							
	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	..	*344.02	35.40	Camptosar (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)	PF
							Hospira Pty Limited (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	HH
							Hospira Pty Limited (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	HH
							Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	HH
							Irinoccord (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Irinoccord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	WQ
							Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	TA
							Irinotecan Actavis (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	TA
							Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	TA
							Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	AF
							Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	AF
							Irinotecan Alphapharm (irinotecan	AF

Chemotherapy Items for Public Hospital

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium $	Dispensed Price for Max. Amount $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
							hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)	SZ
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Irinotecan Ebewe (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Irinotecan Kabi (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	PK
							Irinotecan Kabi (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	PK
							Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	OE
							Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	OE
							Tecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	WQ
							Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	WQ
							Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	WQ
	TOPOTECAN **Authority required (STREAMLINED)** ***3186*** Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound							
4617B	Injection	3500 mcg	17	..	*371.04	35.40	Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials)	GK
							Topotecan Kabi (topotecan 4 mg injection, 5 x 4 mg vials)	PK

Related Pharmaceutical Benefits (not subject to the revised arrangements) for Public Hospital use

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

ALIMENTARY TRACT AND METABOLISM

ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS
Serotonin (5HT3) antagonists

GRANISETRON

Restricted benefit

Nausea and vomiting

The Clinical criteria is:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

5898K	granisetron 2 mg tablet, 1	2	..	..	*44.44	35.40		Kytril	RO
5899L	granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule	1	..	..	25.42	26.53	[a]	Granisetron Kabi	PK
							[a]	Kytril	RO

ONDANSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

5848T	ondansetron 4 mg/5 mL oral liquid, 50 mL	‡1	..	..	80.78	35.40		Zofran syrup 50 mL	GK
5967C	ondansetron 4 mg tablet, 4	1	..	..	16.17	17.28	[a]	APO-Ondansetron	TX
							[a]	Ondansetron-DRLA	RZ
							[a]	Ondaz	SZ
							[a]	Onsetron 4	ZP
							[a]	Zofran	GK
5968D	ondansetron 8 mg tablet, 4	1	..	..	25.33	26.44	[a]	APO-Ondansetron	TX
							[a]	Ondansetron-DRLA	RZ
							[a]	Ondaz	SZ
							[a]	Onsetron 8	ZP
							[a]	Zofran	GK
5971G	ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	1	..	..	1.93	5.50	[a]	Ondansetron Alphapharm	AF
							[a]	Ondansetron-Claris	AE
							[a]	Ondaz	SZ
							[a]	Onsetron	ZP
							[a]	Zofran	GK
5972H	ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	1	..	..	3.06	5.50	[a]	Ondansetron Alphapharm	AF
							[a]	Ondansetron-Claris	AE
							[a]	Ondaz	SZ
							[a]	Onsetron	ZP
							[a]	Zofran	GK

ONDANSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

Note

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
	Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution.								
5857G	ONDANSETRON Tablet (orally disintegrating) 4 mg, 4	1	..	..	16.17	17.28	[a]	Ondansetron ODT-DRLA	RZ
							[a]	Onsetron ODT 4	WQ
5969E	ondansetron 4 mg wafer, 4	1	..	..	16.17	17.28	[a]	Ondaz Zydis	SZ
							[a]	Zofran Zydis	GK

ONDANSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

Note

Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	
5858H	ONDANSETRON Tablet (orally disintegrating) 8 mg, 4	1	..	..	25.33	25.33	[a]	Ondansetron ODT-DRLA	RZ
							[a]	Onsetron ODT 8	WQ
5970F	ondansetron 8 mg wafer, 4	1	..	..	25.33	25.33	[a]	Ondaz Zydis	SZ
							[a]	Zofran Zydis	GK

PALONOSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration

Note

No applications for increased maximum quantities will be authorised. Palonosetron is not PBS-subsidised for administration with oral 5-HT3 antagonists.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
5853C	palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial	1	..	..	34.36	34.36	Aloxi	TS

TROPISETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
5986C	tropisetron 5 mg capsule, 2	1	..	..	37.02	35.40	Navoban	NV
5987D	tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule	1	..	..	18.50	18.50	Navoban	NV

Other antiemetics

APREPITANT

Authority required (STREAMLINED)

3619

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone, where any 1 of the following chemotherapy agents are to be administered:

(a) altretamine;

(b) carmustine;

(c) cisplatin when a single dose constitutes a cycle of chemotherapy;

(d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater;

(e) dacarbazine;

(f) procarbazine when a single dose constitutes a cycle of chemotherapy;

(g) streptozocin.

No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy

Authority required (STREAMLINED)

3620

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5HT3

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered. No more than 1 pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy **Authority required (STREAMLINED)** ***3621*** Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered: (a) arsenic trioxide; (b) azacitidine; (c) carboplatin; (d) cyclophosphamide at a dose of less than 1500 mg per square metre per day; (e) cytarabine at a dose of greater than 1 g per square metre per day; (f) dactinomycin; (g) daunorubicin; (h) doxorubicin; (i) epirubicin; (j) fotemustine; (k) idarubicin; (l) ifosfamide; (m) irinotecan; (n) melphalan; (o) methotrexate at a dose of 250 mg to 1 g per square metre; (p) oxaliplatin; (q) raltitrexed. No more than one pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle **Note** Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy. **Note** No applications for increased maximum quantities and/or repeats will be authorised.							
5888X	aprepitant 125 mg capsule [1 capsule] (&) aprepitant 80 mg capsule [2 capsules], 3	‡1	5	..	112.01	35.40	Emend	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

INTERFERON ALFA-2A

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

3180

Hairy cell leukaemia

Authority required (STREAMLINED)

3899

Myeloproliferative disease with excessive thrombocytosis

5945X	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	15	4	..	*447.00	35.40	Roferon-A	RO

INTERFERON ALFA-2A

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

3895

Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

5946Y	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	15	5	..	*447.00	35.40	Roferon-A	RO
5947B	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	5	..	*223.50	35.40	Roferon-A	RO
5948C	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	5	..	*297.90	35.40	Roferon-A	RO
5949D	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	5	..	*446.90	35.40	Roferon-A	RO

INTERFERON ALFA-2A

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

3899

Myeloproliferative disease with excessive thrombocytosis

5996N	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	4	..	*223.50	35.40	Roferon-A	RO
5997P	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	4	..	*297.90	35.40	Roferon-A	RO
5998Q	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	4	..	*446.90	35.40	Roferon-A	RO

INTERFERON ALFA-2B

Caution

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
	Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
	Authority required (STREAMLINED)							
	3180							
	Hairy cell leukaemia							
5893E	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	3	4	..	*536.22	35.40	Intron A Redipen	MK
	INTERFERON ALFA-2B							
	Caution							
	Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
	Authority required (STREAMLINED)							
	3898							
	Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy							
	Authority required (STREAMLINED)							
	3895							
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy							
5953H	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	3	5	..	*536.22	35.40	Intron A Redipen	MK
5956L	interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	3	5	..	*893.70	35.40	Intron A Redipen	MK

Other immunostimulants

	BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN							
	Restricted benefit							
	Treatment of carcinoma in situ of the urinary bladder							
5901N	Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	3	1	..	*405.00	35.40	ImmuCyst	SW
	BACILLUS CALMETTE AND GUERIN-TICE STRAIN							
	Restricted benefit							
	Primary and relapsing superficial urothelial carcinoma of the bladder							
5902P	Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 x 500 million colony forming units vials	1	1	..	491.83	35.40	OncoTICE	MK

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $		Brand Name and Manufacturer	

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Detoxifying agents for antineoplastic treatment

FOLINIC ACID

Note

For item codes 5890B, 1894Q and 1899Y, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

1894Q	folinic acid 50 mg/5 mL injection, 5 x 5 mL ampoules	2	2	..	*236.10	35.40	a	Calcium Folinate Ebewe	SZ

FOLINIC ACID

Note

For item codes 5890B, 1894Q and 1899Y, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

1899Y	folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules	1	2	..	236.10	35.40	a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF

FOLINIC ACID

Note

For item codes 5886T and 1904F, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

1904F	folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules	1	1	..	218.00	35.40	a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF

FOLINIC ACID

5863N	folinic acid 1 g/100 mL injection, 1 x 100 mL vial	1	1	..	217.91	35.40		Calcium Folinate Ebewe	SZ
5870Y	folinic acid 300 mg/30 mL injection, 1 x 30 mL vial	4	1	..	*254.92	35.40	a	Calcium Folinate Ebewe	SZ
							a	Leucovorin Calcium (Hospira Pty Limited)	HH

FOLINIC ACID

Note

For item codes 5886T and 1904F, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

5886T	folinic acid 100 mg/10 mL injection, 1 x 10 mL vial	10	1	..	*218.00	35.40	a	Calcium Folinate Ebewe	SZ

FOLINIC ACID

Note

For item codes 5890B, 1894Q and 1899Y, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

5890B	folinic acid 50 mg/5 mL injection, 1 x 5 mL vial	10	2	..	*236.10	35.40	a	Leucovorin Calcium (Hospira Pty Limited)	HH

FOLINIC ACID

Restricted benefit

Antidote to folic acid antagonists

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium $	Dispensed Price for Max. Qty $	Maximum Recordable Value for Safety Net $	Brand Name and Manufacturer	
5904R	folinic acid 15 mg tablet, 10	1	..	..	76.00	35.40	Leucovorin Calcium (Hospira Pty Limited)	HH
	MESNA **Restricted benefit** Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide							
5960Q	mesna 400 mg/4 mL injection, 15 x 4 mL ampoules	1	5	..	81.89	35.40	Uromitexan	BX
5961R	mesna 1 g/10 mL injection, 15 x 10 mL ampoules	1	5	..	185.44	35.40	Uromitexan	BX

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