



Australian Government

Department of Health

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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Summary of Changes

Efficient Funding of Chemotherapy (Public Hospital)

Deletions

Deletion – Brand

4361M	<i>Accord Doxorubicin, GN</i> – DOXORUBICIN , doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial
4393F	<i>Farine, GN</i> – FLUDARABINE , fludarabine phosphate 50 mg injection, 1 x 50 mg vial
4393F	<i>Fludarabine ACT, VN</i> – FLUDARABINE , fludarabine phosphate 50 mg injection, 1 x 50 mg vial
4393F	<i>Fludarabine Actavis, UA</i> – FLUDARABINE , fludarabine phosphate 50 mg injection, 1 x 50 mg vial
4451G	<i>Tecan, GN</i> – IRINOTECAN , irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial
4451G	<i>Irinotecan Actavis, UA</i> – IRINOTECAN , irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial
4451G	<i>Tecan, GN</i> – IRINOTECAN , irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial
4542C	<i>Oxaliplatin Actavis, UA</i> – OXALIPLATIN , oxaliplatin 50 mg injection, 1 x 50 mg vial
4542C	<i>Oxaliplatin Actavis, UA</i> – OXALIPLATIN , oxaliplatin 100 mg injection, 1 x 100 mg vial
4542C	<i>Oxaliccord, GN</i> – OXALIPLATIN , oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial

Efficient Funding of Chemotherapy (Private Hospital)

Deletions

Deletion – Brand

7229L	<i>Accord Doxorubicin, GN</i> – DOXORUBICIN , doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial
7233Q	<i>Farine, GN</i> – FLUDARABINE , fludarabine phosphate 50 mg injection, 1 x 50 mg vial
7233Q	<i>Fludarabine ACT, VN</i> – FLUDARABINE , fludarabine phosphate 50 mg injection, 1 x 50 mg vial
7233Q	<i>Fludarabine Actavis, UA</i> – FLUDARABINE , fludarabine phosphate 50 mg injection, 1 x 50 mg vial
7249M	<i>Tecan, GN</i> – IRINOTECAN , irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial
7249M	<i>Irinotecan Actavis, UA</i> – IRINOTECAN , irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial
7249M	<i>Tecan, GN</i> – IRINOTECAN , irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial
7253R	<i>Oxaliplatin Actavis, UA</i> – OXALIPLATIN , oxaliplatin 50 mg injection, 1 x 50 mg vial
7253R	<i>Oxaliplatin Actavis, UA</i> – OXALIPLATIN , oxaliplatin 100 mg injection, 1 x 100 mg vial
7253R	<i>Oxaliccord, GN</i> – OXALIPLATIN , oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial

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 Department of Human Services.

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 Department of Human Services' website at www.humanservices.gov.au

Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines

Premium Free Dispensing Incentive payments will commence for eligible PBS listed products dispensed from 1 August 2008. Premium Free Dispensing Incentive payments will be available to approved suppliers to dispense a substitutable, premium-free medicine. The payment will be available only for PBS items which attract a Government subsidy. This includes PBS items supplied to DVA entitled consumers.

A number of conditions and criteria apply to receive this payment. Scripts will be assessed for validity and the Premium Free Dispensing Incentive payment will be paid by the Department of Human Services. Further information on this payment can be found on the Department of Human Services' website at:

www.medicareaustralia.gov.au/provider/pbs/pharmacists/reforms.jsp#dispensing

Remuneration arrangements

Fees payable per item claimed:

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

- Ready Prepared Dispensing Fee (\$6.76)
- Preparation fee (\$102.12)
- Distribution fee (\$25.26)
- Diluent fee (\$5.00)

Section 94 Approved Public Hospital Authority

- Preparation fee (\$102.12)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee (\$6.76)
- Preparation fee (\$102.12)
- Distribution fee (\$25.26) (not payable where the drug is trastuzumab)
- Diluent fee (\$5.00)

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

Special Pharmaceutical Benefits for Private Hospital/Private Clinic use

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

ANTINEOPLASTIC AGENTS

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Other cytotoxic antibiotics

BLEOMYCIN SULFATE

Restricted benefit

Germ cell neoplasms

Restricted benefit

Lymphoma

7244G	Injection	30000 iu	11	^s 13.04	*214.72	*227.76	37.70	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)	GN HH
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Chemotherapy Items for Private Hospital/Private Clinic use

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

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

CYCLOPHOSPHAMIDE

7226H	Injection	2800 mg	17	..	*236.22	37.70	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

7248L	Injection	4000 mg	19	..	*399.26	37.70	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	..	*2377.80	37.70	Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&) inert substance diluent [1 x 4 mL ampoule], 1 pack)	SE
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ANTIMETABOLITES

Folic acid analogues

METHOTREXATE

7250N	Injection	250 mg	5	..	*151.14	37.70	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)	GN
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	GN
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Methotrexate MYX (METHOTREXATE Injection 50 mg in 2 mL, 1)	YN
							Methotrexate MYX (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	YN

METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen.

7251P	Injection	20000 mg	*1005.54	37.70	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	GN

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	
							in 2 mL, 1)	
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	GN
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Methotrexate MYX (METHOTREXATE Injection 50 mg in 2 mL, 1)	YN
							Methotrexate MYX (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	YN
PEMETREXED								
<u>Authority required (STREAMLINED)</u>								
4792								
Locally advanced or metastatic non-small cell lung cancer								
Clinical criteria:								
Patient must have received prior treatment with platinum-based chemotherapy.								
The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated								
Doses greater than 500 mg per metre squared BSA are not PBS-subsidised								
<u>Authority required (STREAMLINED)</u>								
4789								
Mesothelioma								
Clinical criteria:								
The treatment must be in combination with cisplatin.								
The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated								
Doses greater than 500 mg per metre squared BSA are not PBS-subsidised								
7255W	Injection	1100 mg	5	..	*3623.85	37.70	Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial)	LY
							Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial)	LY
RALTITREXED								
<u>Authority required (STREAMLINED)</u>								
3185								
For use as a single agent in the treatment of advanced colorectal cancer								
7256X	Injection	7 mg	8	..	*1474.38	37.70	Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial)	HH
<i>Purine analogues</i>								
CLADRIBINE								
<u>Authority required (STREAMLINED)</u>								
3180								
Hairy cell leukaemia								
7225G	Injection	17 mg	6	..	*1471.30	37.70	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								
<u>Authority required (STREAMLINED)</u>								
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								
<u>Note</u>								
Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical								

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	
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	..	*166.38	37.70	Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)	GZ
							Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)	SZ
Pyrimidine analogues								
CYTARABINE								
7227J	Injection	7000 mg	15	..	*873.44	37.70	Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)	PF
FLUOROURACIL								
<u>Restricted benefit</u>								
For patients requiring administration of fluorouracil by intravenous infusion.								
7234R	Injection	5500 mg	11	..	*168.92	37.70	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
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH
<hr/>								
FLUOROURACIL								
<u>Restricted benefit</u>								
For patients requiring administration of fluorouracil by intravenous injection.								
7239B	Injection	1000 mg	23	..	*144.69	37.70	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
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH
GEMCITABINE								
<u>Caution</u>								
Pharmaceutical benefits containing gemcitabine may have different concentrations.								
<u>Note</u>								
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.								
<u>Note</u>								
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.								
<u>Note</u>								
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	..	*194.22	37.70	DBL Gemcitabine Injection (gemcitabine 1 g/26.3 mL injection, 1 x 26.3 mL vial)	HH
							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

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/5.3 mL injection, 1 x 5.3 mL vial)	
							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)	GN
							Gemaccord (gemcitabine 200 mg injection, 1 x 200 mg vial)	GN
							Gemcitabine Actavis (gemcitabine 1 g injection, 1 x 1 g vial)	GN
							Gemcitabine Actavis 2000 (gemcitabine 2 g injection, 1 x 2 g vial)	GN
							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 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 500 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Gemcitabine Kabi (gemcitabine 1 g injection, 1 x 1 g 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
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS								
<i>Vinca alkaloids and analogues</i>								
VINBLASTINE								
7261E	Injection	20 mg	17	..	*212.08	37.70	Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)	HH
VINCRIStINE								
7262F	Injection	2 mg	7	..	*159.66	37.70	Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)	HH
VINORELBINE								
7263G	Injection	70 mg	7	..	*211.45	37.70	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
<i>Podophyllotoxin derivatives</i>								
ETOPOSIDE								
7237X	Injection	440 mg	14	..	*333.19	37.70	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								

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	
CABAZITAXEL								
<u>Authority required (STREAMLINED)</u>								
4662								
Castration resistant metastatic carcinoma of the prostate								
Clinical criteria:								
The treatment must be in combination with prednisone or prednisolone,								
AND								
The treatment must not be used in combination with abiraterone,								
AND								
Patient must have failed treatment with docetaxel due to resistance or intolerance,								
AND								
Patient must have a WHO performance status of 2 or less,								
AND								
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.								
Note								
Special Pricing Arrangements apply.								
7236W	Injection	55 mg	5	..	*6023.88	37.70	Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1)	SW
DOCETAXEL								
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 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, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel powder for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.								
10158P	Injection	250 mg	5	..	*201.29	37.70	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 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Dotax (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	RZ
							Dotax (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	RZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	GN
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	GN
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW
PACLITAXEL								
7254T	Injection	450 mg	3	..	*214.71	37.70	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
							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)	UA
							Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	UA

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, 1 x 25 mL vial)	
							Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	UA
							Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	UA
							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 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
							Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	GN
							Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	GN
							Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	GN
							Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	GN

PACLITAXEL NANOPARTICLE ALBUMIN BOUND

Authority required (STREAMLINED)

4657

Stage IV (metastatic) adenocarcinoma of the pancreas

Clinical criteria:

The treatment must be in combination with gemcitabine,

AND

The condition must not have been treated previously with PBS-subsidised therapy,

AND

Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note

Not for use as neoadjuvant or adjuvant therapy.

10150F	Injection	275 mg	11	..	*1391.76	37.70	Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial)	TS
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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	..	*2618.04	37.70	Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial)	TS
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CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN

7229L	Injection/intravenous	135 mg	11	..	*170.06	37.70	Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	GN
							Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Doxorubicin MYX (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	YN
							Doxorubicin SZ (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	HX
							Doxorubicin SZ (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	HX

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)	
							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								
<u>Authority required (STREAMLINED)</u>								
4786								
Advanced epithelial ovarian cancer								
Clinical criteria:								
Patient must have failed a first-line platinum-based chemotherapy regimen.								
<u>Authority required (STREAMLINED)</u>								
4791								
Metastatic breast cancer								
Clinical criteria:								
The treatment must be as monotherapy,								
AND								
Patient must have failed prior therapy which included capecitabine and a taxane.								
<u>Authority required (STREAMLINED)</u>								
4787								
Metastatic breast cancer								
Clinical criteria:								
The treatment must be as monotherapy,								
AND								
Patient must have a contraindication to therapy with capecitabine and/or a taxane.								
7230M	Injection	100 mg	5	..	*2701.08	37.70	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
							Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	ZF
							Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)	ZF
EPIRUBICIN								
7231N	Injection/intraves ical	220 mg	5	..	*196.17	37.70	DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	HH
							Epirubicin ACT (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	VN
							Epirubicin ACT (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	VN
							Epirubicin ACT (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	VN
							Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	UA
							Epirubicin Actavis 20 (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)	UA
							Epirubicin Kabi (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	PK
							Epirubicin SZ (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	HX
							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

IDARUBICIN**Restricted benefit**

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	
Acute myelogenous leukaemia								
7247K	Injection	30 mg	5	..	*515.37	37.70	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	..	*274.46	37.70	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
OTHER ANTINEOPLASTIC AGENTS								
<i>Platinum compounds</i>								
CARBOPLATIN								
7222D	Injection	900 mg	5	..	*194.80	37.70	Carbaccord (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	GN
							Carbaccord (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)	GN
							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
CISPLATIN								
7224F	Injection	220 mg	14	..	*167.44	37.70	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
OXALIPLATIN								
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	..	*171.60	37.70	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

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	
							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
							Oxallicord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	GN
							Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	PK
							Oxaliplatin MYX (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	YN
							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
							Oxaliplatin SZ (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	HX

Monoclonal antibodies

BEVACIZUMAB

Authority required (STREAMLINED)

4584

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition,

AND

Patient must not have progressive disease,

AND

The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks,

AND

The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

Note

Special Pricing Arrangements apply.

10114H	Injection	900 mg	11	..	*4063.58	37.70	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

BEVACIZUMAB

Authority required (STREAMLINED)

4814

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm) only if the patient presents with Stage IIIB or Stage IIIC disease,

AND

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

AND

The condition must be previously untreated,

AND

The treatment must be commenced in combination with platinum-based 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 treatment must not exceed a dose of 7.5 mg per kg every 3 weeks,							
	AND							
	The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.							
	The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.							
	Note							
	Special Pricing Arrangements apply.							
10120P	Injection	900 mg	5	..	*4063.58	37.70	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
	BEVACIZUMAB							
	<u>Authority required (STREAMLINED)</u>							
	4594							
	Metastatic colorectal cancer							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	The condition must be previously untreated,							
	AND							
	Patient must have a WHO performance status of 0 or 1,							
	AND							
	The treatment must be in combination with first-line chemotherapy,							
	AND							
	The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR							
	The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.							
	The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.							
	<u>Authority required (STREAMLINED)</u>							
	4587							
	Metastatic colorectal cancer							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition,							
	AND							
	Patient must not have progressive disease,							
	AND							
	The treatment must be in combination with first-line chemotherapy,							
	AND							
	The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR							
	The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.							
	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.							
7243F	Injection	900 mg	11	..	*4063.58	37.70	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

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
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BRENTUXIMAB VEDOTIN

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be for curative intent,

AND

Patient must have undergone appropriate prior front-line curative intent chemotherapy,

AND

Patient must demonstrate relapsed or chemotherapy-refractory disease.

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Systemic anaplastic large cell lymphoma Brentuximab PBS Authority Application - Supporting Information Form which includes the following:
 - (i) a histology report including evidence of the tumour's CD30 positivity from a biopsy subsequent to the most recently delivered prior treatment with radiation, chemotherapy, biologics, immunotherapy or other agents;
 - (ii) The date of initial diagnosis of systemic anaplastic large cell lymphoma;
 - (iii) Dates of commencement and completion of front-line curative intent chemotherapy;
 - (iv) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory;
 - (v) a declaration of whether the patient has had, or is planned to have, a transplant

A maximum quantity and number of repeats to provide for an initial course of brentuximab vedotin of 4 cycles will be authorised as part of the initiating restriction.

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

No increase in the maximum number of repeats may be authorised.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

Special Pricing Arrangements apply.

10172J	Injection	200 mg	3	..	*21409.14	37.70	Adcetris (brentuximab vedotin 50mg injection, 1 x 50 mg vial)	TK
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BRENTUXIMAB VEDOTIN

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must not have progressive disease,

AND

Patient must have previously been issued with an authority prescription for this drug.

The treatment must not exceed a lifetime total of 16 cycles.

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
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Note

No increase in the maximum number of repeats may be authorised.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

Special Pricing Arrangements apply.

10180T	Injection	200 mg	11	..	*21409.14	37.70	Adcetris (brentuximab vedotin 50mg injection, 1 x 50 mg vial)	TK
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CETUXIMAB**Authority required (STREAMLINED)**

4794

Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be for the week prior to radiotherapy,

AND

Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Authority required (STREAMLINED)

4785

Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be in combination with radiotherapy,

AND

Patient must be unable to tolerate cisplatin.

Note

No increase in the maximum number of repeats may be authorised.

7223E	Injection	880 mg	*3274.26	37.70	Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

CETUXIMAB**Authority required (STREAMLINED)**

4788

Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be in combination with radiotherapy,

AND

Patient must be unable to tolerate cisplatin; OR

Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

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	..	*2231.81	37.70	Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

CETUXIMAB**Authority required (STREAMLINED)**

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
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4779

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have RAS wild-type metastatic colorectal cancer,

AND

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

AND

The condition must have failed to respond to first-line chemotherapy,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with an irinotecan based therapy,

AND

The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.

Note

Special Pricing Arrangements apply.

Note

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

7242E	Injection	880 mg	*3274.26	37.70	Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

CETUXIMAB

Authority required (STREAMLINED)

4771

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy,

AND

Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with an irinotecan based therapy,

AND

The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.

Note

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
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Special Pricing Arrangements apply.

Note

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

7273T	Injection	550 mg	11	..	*2231.81	37.70	Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)	SG
							Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial)	SG

IPILIMUMAB

Authority required (STREAMLINED)

4254

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be as monotherapy,

AND

Patient must not have received prior treatment with ipilimumab,

AND

The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

Note

For patients who commence therapy with ipilimumab:

(i) Decisions concerning efficacy should await completion of the entire induction regimen (four doses) and should be made in conjunction with established criteria for immunological responses. However induction may be ceased or delayed if symptomatic progressive disease or intolerable adverse events occur and if, in the opinion of the clinician, continuation of treatment poses a risk to the patient;

(ii) Tumour responses may occur beyond the initial 12 week induction phase and evaluation for potential later responses should be undertaken regularly for the first year.

Authority required (STREAMLINED)

4261

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be as monotherapy,

AND

Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction),

AND

The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

An initial objective response to treatment is defined as either:

(i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or

(ii) a partial or complete response.

The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

2638W	Injection	360 mg	3	..	*47585.30	37.70	Yervoy (ipilimumab 200 mg/40 mL injection, 1 x 40 mL vial)	BQ
							Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial)	BQ

IPILIMUMAB

Authority required (STREAMLINED)

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	
	4251							
	Unresectable Stage III or Stage IV malignant melanoma							
	Treatment Phase: Completion of induction treatment							
	Clinical criteria:							
	The treatment must be as monotherapy,							
	AND							
	The treatment must be for completion of induction treatment in a patient who commenced induction treatment with ipilimumab prior to 1 August 2013,							
	AND							
	The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) at a maximum dose of 3 mg per kg every 3 weeks.							
	The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.							
	For patients who commenced induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a total of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS subsidised).							
	Note							
	For patients who commence therapy with ipilimumab:							
	(i) Decisions concerning efficacy should await completion of the entire induction regimen (four doses) and should be made in conjunction with established criteria for immunological responses. However induction may be ceased or delayed if symptomatic progressive disease or intolerable adverse events occur and if, in the opinion of the clinician, continuation of treatment poses a risk to the patient;							
	(ii) Tumour responses may occur beyond the initial 12 week induction phase and evaluation for potential later responses should be undertaken regularly for the first year.							
	Authority required (STREAMLINED)							
	4252							
	Unresectable Stage III or Stage IV malignant melanoma							
	Treatment Phase: Completion of re-induction treatment							
	Clinical criteria:							
	The treatment must be as monotherapy,							
	AND							
	Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction) received prior to 1 August 2013,							
	AND							
	The treatment must be for completion of re-induction treatment in a patient who commenced re-induction treatment with ipilimumab prior to 1 August 2013,							
	AND							
	The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) at a maximum dose of 3 mg per kg every 3 weeks.							
	An initial objective response to treatment is defined as either:							
	(i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or							
	(ii) a partial or complete response.							
	The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.							
	For patients who commenced re-induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a maximum of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS-subsidised).							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	A patient may only qualify for PBS-subsidised treatment under this restriction once.							
	Note							
	Special Pricing Arrangements apply.							
2643D	Injection	360 mg	2	..	*47585.30	37.70	Yervoy (ipilimumab 200 mg/40 mL injection, 1 x 40 mL vial) Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial)	BQ BQ

OFATUMUMAB

Authority required (STREAMLINED)

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
	4858						
	Chronic lymphocytic leukaemia (CLL)						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),						
	AND						
	Patient must have previously been issued with an authority prescription for this drug,						
	AND						
	Patient must not have progressive disease,						
	AND						
	Patient must be inappropriate for fludarabine based therapy,						
	AND						
	The treatment must be in combination with chlorambucil.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	Special Pricing Arrangements apply.						
10237T	Injection	1000 mg	5	..	*3594.73	37.70	Arzerra (ofatumumab 1 g/50 mL injection, 50 mL vial) GK

OFATUMUMAB

Authority required (STREAMLINED)

4828

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),

AND

The condition must be previously untreated,

AND

The treatment must be in combination with chlorambucil,

AND

Patient must be inappropriate for fludarabine based therapy.

Note

An initial dose of 1300 mg of PBS-subsidised ofatumumab must be made up of 3 vials of 100 mg and 1 vial of 1000 mg.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

Special Pricing Arrangements apply.

10239X	Injection	1000 mg	5	..	*3594.73	37.70	Arzerra (ofatumumab 1 g/50 mL injection, 50 mL vial) GK
10240Y	Injection	300 mg	*1195.44	37.70	Arzerra (ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials) GK

PANITUMUMAB

Authority required (STREAMLINED)

4784

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have RAS wild-type metastatic colorectal cancer,

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							
Patient must have a WHO performance status of 2 or less,							
AND							
The condition must have failed to respond to first-line chemotherapy,							
AND							
The treatment must be as monotherapy; OR							
The treatment must be in combination with an irinotecan based therapy,							
AND							
The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.							
Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.							
Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.							
<u>Authority required (STREAMLINED)</u>							
4783							
Metastatic colorectal cancer							
Treatment Phase: Continuing treatment							
Clinical criteria:							
Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy,							
AND							
Patient must not have progressive disease,							
AND							
The treatment must be as monotherapy; OR							
The treatment must be in combination with an irinotecan based therapy,							
AND							
The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.							
Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.							
Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.							
<u>Note</u>							
Special Pricing Arrangements apply.							
<u>Note</u>							
Panitumumab is not PBS-subsidised for use in combination with oxaliplatin-based therapies.							
10069Y	Injection	720 mg	5	..	*6033.14	37.70	Vectibix (panitumumab 100 mg/5 mL injection, 1 x 5 mL vial) AN
							Vectibix (panitumumab 400 mg/20 mL injection, 1 x 20 mL vial) AN

RITUXIMAB

Authority required (STREAMLINED)

4674

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

Patient must have demonstrated a partial or complete response to the induction phase of treatment for previously untreated follicular B-cell Non-

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
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Hodgkin's lymphoma, received immediately prior to this current Authority application,

AND

The treatment must be maintenance therapy,

AND

Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

Note

A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

10193L	Injection	800 mg	11	..	*3453.07	37.70	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)**

4677

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

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be for re-induction treatment purposes only,

AND

The condition must have relapsed or be refractory to treatment,

AND

Patient must not receive more than 4 doses under this restriction.

Authority required (STREAMLINED)

4678

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

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be for re-induction treatment purposes only,

AND

The condition must have relapsed or be refractory to treatment,

AND

Patient must not receive more than 4 doses under this restriction.

Note

No increase in the maximum number of repeats may be authorised.

7257Y	Injection	800 mg	3	..	*3453.07	37.70	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)**

4701

Previously untreated CD20 positive diffuse large B-cell non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with 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 condition must be previously untreated,						
	AND						
	The condition must be symptomatic,						
	AND						
	The treatment must be for induction treatment purposes only,						
	AND						
	Patient must not receive more than 8 doses under this restriction.						
	<u>Authority required (STREAMLINED)</u>						
	<i>4726</i>						
	Previously untreated Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma						
	Treatment Phase: Induction treatment						
	Clinical criteria:						
	The treatment must be in combination with chemotherapy,						
	AND						
	The condition must be previously untreated,						
	AND						
	The condition must be symptomatic,						
	AND						
	The treatment must be for induction treatment purposes only,						
	AND						
	Patient must not receive more than 8 doses under this restriction.						
	<u>Note</u>						
	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.						
	<u>Authority required (STREAMLINED)</u>						
	<i>4686</i>						
	Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma						
	Treatment Phase: Maintenance therapy						
	Clinical criteria:						
	The treatment must be maintenance therapy,						
	AND						
	Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application,						
	AND						
	Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
7258B	Injection	800 mg	7	..	*3453.07	37.70	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)

4706

Chronic lymphocytic leukaemia (CLL)

Clinical criteria:

The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),

AND

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
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The treatment must be in combination with chemotherapy.

Note

This drug is not PBS-subsidised for use as monotherapy.

Note

No increase in the maximum number of repeats may be authorised.

7259C	Injection	1100 mg	5	..	*4664.57	37.70	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)

Clinical criteria:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

AND

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

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)

Clinical criteria:

Patient must commence treatment concurrently with adjuvant chemotherapy,

AND

Patient must have undergone surgery,

AND

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

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 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
	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	*3676.29	37.70	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: Continuing treatment (weekly regimen)

Clinical criteria:

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

AND

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

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)

Clinical criteria:

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

AND

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

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

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
	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	..	*2029.51	37.70	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)

Clinical criteria:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

AND

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

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)

Clinical criteria:

Patient must commence treatment concurrently with adjuvant chemotherapy,

AND

Patient must have undergone surgery,

AND

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

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

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
	(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						
7266K	Injection	1000 mg	*7183.52	37.70	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: Continuing treatment (3 weekly regimen)

Clinical criteria:

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

AND

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

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)

Clinical criteria:

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

AND

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

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).

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 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							
7267L	Injection	750 mg	3	..	*5328.95	37.70	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)

4793

Acute promyelocytic leukaemia

Treatment Phase: Induction and consolidation treatment

Clinical criteria:

The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript,

AND

The condition must be relapsed,

AND

Patient must be arsenic naive at induction.

7241D	Injection	18 mg	89	..	*972.86	37.70	Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)	PL
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BORTEZOMIB

Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

Patient must be newly diagnosed,

AND

Patient must be ineligible for high dose chemotherapy,

AND

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

AND

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

AND

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

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
	Symptomatic multiple myeloma						
	Treatment Phase: Initial PBS-subsidised treatment						
	Clinical criteria:						
	Patient must be newly diagnosed,						
	AND						
	Patient must have severe acute renal failure,						
	AND						
	Patient must require dialysis; OR						
	Patient must be at high risk of requiring dialysis in the opinion of a nephrologist,						
	AND						
	The treatment must be in combination with a corticosteroid and/or cyclophosphamide,						
	AND						
	Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,						
	AND						
	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.						
7238Y	Injection	3000 mcg	31	..	*1667.04	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) JC

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
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BORTEZOMIB

Authority required

Multiple myeloma

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

Clinical criteria:

The condition must be confirmed by a histological diagnosis,

AND

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND

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.

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
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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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

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

AND

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

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
	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	..	*1921.70	37.70	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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

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

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

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
	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	..	*1921.70	37.70	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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

Patient must have progressive disease,

AND

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

AND

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

AND

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND

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

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
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(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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

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

AND

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

Chemotherapy Items for Private Hospital/Private Clinic use

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	(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.						
7271Q	Injection	3000 mcg	15	..	*1921.70	37.70	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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

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

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:

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
	(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.						
7272R	Injection	3000 mcg	11	..	*1921.70	37.70	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

Clinical criteria:

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

AND

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

AND

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

AND

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

AND

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

AND

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

Clinical criteria:

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

AND

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

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
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AND

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

AND

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

AND

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).

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	..	*1667.04	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
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BORTEZOMIB**Authority required**

Symptomatic multiple myeloma

Clinical criteria:

Patient must be newly diagnosed,

AND

Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation,

AND

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

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 treatment must be in combination with chemotherapy,								
AND								
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.								
7275X	Injection	3000 mcg	15	..	*1667.04	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
ERIBULIN								
Authority required								
Locally advanced or metastatic breast cancer								
Clinical criteria:								
Patient must have progressive disease,								
AND								
Patient must have failed at least two prior chemotherapeutic regimens for this condition,								
AND								
The treatment must be the sole PBS-subsidised therapy for this condition.								
Note								
A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.								
Note								
Special Pricing Arrangements apply.								
10140Q	Injection	3 mg	13	..	*1543.14	37.70	Halaven (eribulin mesilate 1 mg/2 mL injection, 1 x 2 mL vial)	EI
IRINOTECAN								
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	..	*244.14	37.70	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)	GN

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	
							Irinoccord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	GN
							Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	UA
							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 MYX (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	YN
							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 500 mg/25 mL injection, 1 x 25 mL vial)	GN

TOPOTECAN
Authority required (STREAMLINED)
3186

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

7260D	Injection	3500 mcg	17	..	*210.12	37.70	Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials)	GK
							Topotecan Agila (topotecan 4 mg injection, 1 x 4 mg vial)	AF
							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
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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Other cytotoxic antibiotics

BLEOMYCIN SULFATE

Restricted benefit

Germ cell neoplasms

Restricted benefit

Lymphoma

4433H	Injection	30000 iu	11	^s 11.86	*170.82	*182.68	37.70	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)	GN HH
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Chemotherapy Items for Public Hospital use

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

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

CYCLOPHOSPHAMIDE

4327R	Injection	2800 mg	17	..	*190.38	37.70	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

4448D	Injection	4000 mg	19	..	*344.24	37.70	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	..	*2270.78	37.70	Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&) inert substance diluent [1 x 4 mL ampoule], 1 pack)	SE
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ANTIMETABOLITES

Folic acid analogues

METHOTREXATE

4502Y	Injection	250 mg	5	..	*112.57	37.70	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)	GN
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	GN
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Methotrexate MYX (METHOTREXATE Injection 50 mg in 2 mL, 1)	YN
							Methotrexate MYX (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	YN

METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen.

4512L	Injection	20000 mg	*935.20	37.70	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	GN

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							in 2 mL, 1)	
							Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	GN
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							Methotrexate MYX (METHOTREXATE Injection 50 mg in 2 mL, 1)	YN
							Methotrexate MYX (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)	YN
PEMETREXED								
<u>Authority required (STREAMLINED)</u>								
4792								
Locally advanced or metastatic non-small cell lung cancer								
Clinical criteria:								
Patient must have received prior treatment with platinum-based chemotherapy.								
The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated								
Doses greater than 500 mg per metre squared BSA are not PBS-subsidised								
<u>Authority required (STREAMLINED)</u>								
4789								
Mesothelioma								
Clinical criteria:								
The treatment must be in combination with cisplatin.								
The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated								
Doses greater than 500 mg per metre squared BSA are not PBS-subsidised								
4600D	Injection	1100 mg	5	..	*3533.79	37.70	Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial)	LY
							Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial)	LY
RALTITREXED								
<u>Authority required (STREAMLINED)</u>								
3185								
For use as a single agent in the treatment of advanced colorectal cancer								
4610P	Injection	7 mg	8	..	*1386.00	37.70	Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial)	HH
<i>Purine analogues</i>								
CLADRIBINE								
<u>Authority required (STREAMLINED)</u>								
3180								
Hairy cell leukaemia								
4326Q	Injection	17 mg	6	..	*1383.04	37.70	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								
<u>Authority required (STREAMLINED)</u>								
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								
<u>Note</u>								
Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical								

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
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	..	*125.80	37.70	Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)	GZ
							Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)	SZ
Pyrimidine analogues								
CYTARABINE								
4357H	Injection	7000 mg	15	..	*808.42	37.70	Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)	PF
FLUOROURACIL								
<u>Restricted benefit</u>								
For patients requiring administration of fluorouracil by intravenous infusion.								
4394G	Injection	5500 mg	11	..	*128.68	37.70	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
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH
FLUOROURACIL								
<u>Restricted benefit</u>								
For patients requiring administration of fluorouracil by intravenous injection.								
4431F	Injection	1000 mg	23	..	*106.95	37.70	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
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH
GEMCITABINE								
<u>Caution</u>								
Pharmaceutical benefits containing gemcitabine may have different concentrations.								
<u>Note</u>								
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.								
<u>Note</u>								
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.								
<u>Note</u>								
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	..	*152.19	37.70	DBL Gemcitabine Injection (gemcitabine 1 g/26.3 mL injection, 1 x 26.3 mL vial)	HH
							DBL Gemcitabine Injection (gemcitabine 2 g/52.6 mL injection, 1 x 52.6 mL vial)	HH
							DBL Gemcitabine Injection (gemcitabine 200 mg/26.3 mL injection, 1 x 26.3 mL vial)	HH

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							mg/5.3 mL injection, 1 x 5.3 mL vial)	
							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)	GN
							Gemaccord (gemcitabine 200 mg injection, 1 x 200 mg vial)	GN
							Gemcitabine Actavis (gemcitabine 1 g injection, 1 x 1 g vial)	GN
							Gemcitabine Actavis 2000 (gemcitabine 2 g injection, 1 x 2 g vial)	GN
							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 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 500 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Gemcitabine Kabi (gemcitabine 1 g injection, 1 x 1 g 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

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

	VINBLASTINE							
4618C	Injection	20 mg	17	..	*168.42	37.70	Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)	HH
	VINCRIStINE							
4619D	Injection	2 mg	7	..	*119.96	37.70	Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)	HH
	VINORELBINE							
4620E	Injection	70 mg	7	..	*167.85	37.70	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	..	*278.52	37.70	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

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
CABAZITAXEL								
<u>Authority required (STREAMLINED)</u>								
4662								
Castration resistant metastatic carcinoma of the prostate								
Clinical criteria:								
The treatment must be in combination with prednisone or prednisolone,								
AND								
The treatment must not be used in combination with abiraterone,								
AND								
Patient must have failed treatment with docetaxel due to resistance or intolerance,								
AND								
Patient must have a WHO performance status of 2 or less,								
AND								
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.								
Note								
Special Pricing Arrangements apply.								
4376H	Injection	55 mg	5	..	*5916.86	37.70	Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1)	SW
DOCETAXEL								
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 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, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel powder for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.								
10148D	Injection	250 mg	5	..	*158.59	37.70	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 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Dotax (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	RZ
							Dotax (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	RZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	GN
							Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	GN
							Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)	SW
							Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)	SW
PACLITAXEL								
4567J	Injection	450 mg	3	..	*170.82	37.70	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
							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)	UA
							Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	UA

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							injection, 1 x 25 mL vial)	
							Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	UA
							Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	UA
							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 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
							Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	GN
							Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	GN
							Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)	GN
							Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	GN

PACLITAXEL NANOPARTICLE ALBUMIN BOUND

Authority required (STREAMLINED)

4657

Stage IV (metastatic) adenocarcinoma of the pancreas

Clinical criteria:

The treatment must be in combination with gemcitabine,

AND

The condition must not have been treated previously with PBS-subsidised therapy,

AND

Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note

Not for use as neoadjuvant or adjuvant therapy.

10165B	Injection	275 mg	11	..	*1306.56	37.70	Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial)	TS
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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	..	*2511.00	37.70	Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial)	TS
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CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN								
4361M	Injection/intravenous	135 mg	11	..	*129.51	37.70	Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	GN
							Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Doxorubicin MYX (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	YN
							Doxorubicin SZ (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	HX
							Doxorubicin SZ (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	HX

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							mg/100 mL injection, 1 x 100 mL vial)	
							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								
<u>Authority required (STREAMLINED)</u>								
4786								
Advanced epithelial ovarian cancer								
Clinical criteria:								
Patient must have failed a first-line platinum-based chemotherapy regimen.								
<u>Authority required (STREAMLINED)</u>								
4791								
Metastatic breast cancer								
Clinical criteria:								
The treatment must be as monotherapy,								
AND								
Patient must have failed prior therapy which included capecitabine and a taxane.								
<u>Authority required (STREAMLINED)</u>								
4787								
Metastatic breast cancer								
Clinical criteria:								
The treatment must be as monotherapy,								
AND								
Patient must have a contraindication to therapy with capecitabine and/or a taxane.								
4364Q	Injection	100 mg	5	..	*2594.06	37.70	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
							Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)	ZF
							Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)	ZF
EPIRUBICIN								
4375G	Injection/intraves ical	220 mg	5	..	*153.96	37.70	DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	HH
							Epirubicin ACT (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	VN
							Epirubicin ACT (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	VN
							Epirubicin ACT (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	VN
							Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	UA
							Epirubicin Actavis 20 (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)	UA
							Epirubicin Kabi (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	PK
							Epirubicin SZ (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	HX
							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

IDARUBICIN**Restricted benefit**

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Acute myelogenous leukaemia								
4440Q	Injection	30 mg	5	..	*460.35	37.70	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	..	*225.14	37.70	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
OTHER ANTINEOPLASTIC AGENTS								
<i>Platinum compounds</i>								
CARBOPLATIN								
4309T	Injection	900 mg	5	..	*152.72	37.70	Carbaccord (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)	GN
							Carbaccord (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)	GN
							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
CISPLATIN								
4319H	Injection	220 mg	14	..	*126.72	37.70	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
OXALIPLATIN								
<u>Note</u>								
Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 50 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 50 mg are equivalent for the purposes of substitution.								
<u>Note</u>								
Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 100 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 100 mg are equivalent for the purposes of substitution.								
4542C	Injection	300 mg	11	..	*130.89	37.70	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

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							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
							Oxallicord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	GN
							Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	PK
							Oxaliplatin MYX (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	YN
							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
							Oxaliplatin SZ (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	HX

Monoclonal antibodies

BEVACIZUMAB

Authority required (STREAMLINED)

4814

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm) only if the patient presents with Stage IIIB or Stage IIIC disease,

AND

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

AND

The condition must be previously untreated,

AND

The treatment must be commenced in combination with platinum-based chemotherapy,

AND

The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks,

AND

The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Note

Special Pricing Arrangements apply.

10115J	Injection	900 mg	5	..	*3972.12	37.70	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

BEVACIZUMAB

Authority required (STREAMLINED)

4584

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition,								
AND								
Patient must not have progressive disease,								
AND								
The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks,								
AND								
The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.								
Note								
Special Pricing Arrangements apply.								
10121Q	Injection	900 mg	11	..	*3972.12	37.70	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

BEVACIZUMAB

Authority required (STREAMLINED)

4594

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be previously untreated,

AND

Patient must have a WHO performance status of 0 or 1,

AND

The treatment must be in combination with first-line chemotherapy,

AND

The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR

The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority required (STREAMLINED)

4587

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition,

AND

Patient must not have progressive disease,

AND

The treatment must be in combination with first-line chemotherapy,

AND

The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR

The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

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.

4400N	Injection	900 mg	11	..	*3972.12	37.70	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

BRENTUXIMAB VEDOTIN

Chemotherapy Items for Public Hospital use

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

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be for curative intent,

AND

Patient must have undergone appropriate prior front-line curative intent chemotherapy,

AND

Patient must demonstrate relapsed or chemotherapy-refractory disease.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Systemic anaplastic large cell lymphoma Brentuximab PBS Authority Application - Supporting Information Form which includes the following:

(i) a histology report including evidence of the tumour's CD30 positivity from a biopsy subsequent to the most recently delivered prior treatment with radiation, chemotherapy, biologics, immunotherapy or other agents;

(ii) The date of initial diagnosis of systemic anaplastic large cell lymphoma;

(iii) Dates of commencement and completion of front-line curative intent chemotherapy;

(iv) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory;

(v) a declaration of whether the patient has had, or is planned to have, a transplant

A maximum quantity and number of repeats to provide for an initial course of brentuximab vedotin of 4 cycles will be authorised as part of the initiating restriction.

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

No increase in the maximum number of repeats may be authorised.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

Special Pricing Arrangements apply.

10166C	Injection	200 mg	3	..	*21302.12	37.70	Adcetris (brentuximab vedotin 50mg injection, 1 x 50 mg vial)	TK
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BRENTUXIMAB VEDOTIN

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must not have progressive disease,

AND

Patient must have previously been issued with an authority prescription for this drug.

The treatment must not exceed a lifetime total of 16 cycles.

Note

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
No increase in the maximum number of repeats may be authorised.							
Note							
No increase in the maximum quantity or number of units may be authorised.							
Note							
Special Pricing Arrangements apply.							
10171H	Injection	200 mg	11	..	*21302.12	37.70	Adcetris (brentuximab vedotin 50mg injection, 1 x 50 mg vial) TK
CETUXIMAB							
<u>Authority required (STREAMLINED)</u>							
4794							
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx							
Treatment Phase: Initial treatment							
Clinical criteria:							
The treatment must be for the week prior to radiotherapy,							
AND							
Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.							
<u>Authority required (STREAMLINED)</u>							
4785							
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx							
Treatment Phase: Initial treatment							
Clinical criteria:							
The treatment must be in combination with radiotherapy,							
AND							
Patient must be unable to tolerate cisplatin.							
Note							
No increase in the maximum number of repeats may be authorised.							
4312Y	Injection	880 mg	*3171.12	37.70	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							
<u>Authority required (STREAMLINED)</u>							
4788							
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx							
Treatment Phase: Continuing treatment							
Clinical criteria:							
The treatment must be in combination with radiotherapy,							
AND							
Patient must be unable to tolerate cisplatin; OR							
Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.							
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	..	*2148.12	37.70	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							
<u>Authority required (STREAMLINED)</u>							
4779							

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Metastatic colorectal cancer						
	Treatment Phase: Initial treatment						
	Clinical criteria:						
	Patient must have RAS wild-type metastatic colorectal cancer,						
	AND						
	Patient must have a WHO performance status of 2 or less,						
	AND						
	The condition must have failed to respond to first-line chemotherapy,						
	AND						
	The treatment must be as monotherapy; OR						
	The treatment must be in combination with an irinotecan based therapy,						
	AND						
	The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.						
	Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.						
	Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.						
	Note						
	Special Pricing Arrangements apply.						
	Note						
	Cetuximab is not PBS-subsidised for use in combination with oxaliplatin-based therapies.						
4436L	Injection	880 mg	*3171.12	37.70	Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial) SG Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) SG

CETUXIMAB

Authority required (STREAMLINED)

4771

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy,

AND

Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with an irinotecan based therapy,

AND

The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.

Note

Special Pricing Arrangements apply.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Note								
Cetuximab is not PBS-subsidised for use in combination with oxaliplatin-based therapies.								
4731B	Injection	550 mg	11	..	*2148.12	37.70	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
IPILIMUMAB								
<u>Authority required (STREAMLINED)</u>								
4254								
Unresectable Stage III or Stage IV malignant melanoma								
Treatment Phase: Induction treatment								
Clinical criteria:								
The treatment must be as monotherapy,								
AND								
Patient must not have received prior treatment with ipilimumab,								
AND								
The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.								
The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.								
Note								
For patients who commence therapy with ipilimumab:								
(i) Decisions concerning efficacy should await completion of the entire induction regimen (four doses) and should be made in conjunction with established criteria for immunological responses. However induction may be ceased or delayed if symptomatic progressive disease or intolerable adverse events occur and if, in the opinion of the clinician, continuation of treatment poses a risk to the patient;								
(ii) Tumour responses may occur beyond the initial 12 week induction phase and evaluation for potential later responses should be undertaken regularly for the first year.								
<u>Authority required (STREAMLINED)</u>								
4261								
Unresectable Stage III or Stage IV malignant melanoma								
Treatment Phase: Re-induction treatment								
Clinical criteria:								
The treatment must be as monotherapy,								
AND								
Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction),								
AND								
The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.								
An initial objective response to treatment is defined as either:								
(i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or								
(ii) a partial or complete response.								
The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.								
Note								
No increase in the maximum number of repeats may be authorised.								
Note								
Special Pricing Arrangements apply.								
2641B	Injection	360 mg	3	..	*47478.28	37.70	Yervoy (ipilimumab 200 mg/40 mL injection, 1 x 40 mL vial)	BQ
							Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial)	BQ

IPILIMUMAB

Authority required (STREAMLINED)

4251

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Unresectable Stage III or Stage IV malignant melanoma						
	Treatment Phase: Completion of induction treatment						
	Clinical criteria:						
	The treatment must be as monotherapy,						
	AND						
	The treatment must be for completion of induction treatment in a patient who commenced induction treatment with ipilimumab prior to 1 August 2013,						
	AND						
	The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) at a maximum dose of 3 mg per kg every 3 weeks.						
	The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.						
	For patients who commenced induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a total of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS subsidised).						
	Note						
	For patients who commence therapy with ipilimumab:						
	(i) Decisions concerning efficacy should await completion of the entire induction regimen (four doses) and should be made in conjunction with established criteria for immunological responses. However induction may be ceased or delayed if symptomatic progressive disease or intolerable adverse events occur and if, in the opinion of the clinician, continuation of treatment poses a risk to the patient;						
	(ii) Tumour responses may occur beyond the initial 12 week induction phase and evaluation for potential later responses should be undertaken regularly for the first year.						
	Authority required (STREAMLINED)						
	4252						
	Unresectable Stage III or Stage IV malignant melanoma						
	Treatment Phase: Completion of re-induction treatment						
	Clinical criteria:						
	The treatment must be as monotherapy,						
	AND						
	Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction) received prior to 1 August 2013,						
	AND						
	The treatment must be for completion of re-induction treatment in a patient who commenced re-induction treatment with ipilimumab prior to 1 August 2013,						
	AND						
	The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) at a maximum dose of 3 mg per kg every 3 weeks.						
	An initial objective response to treatment is defined as either:						
	(i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or						
	(ii) a partial or complete response.						
	The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.						
	For patients who commenced re-induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a maximum of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS-subsidised).						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	A patient may only qualify for PBS-subsidised treatment under this restriction once.						
	Note						
	Special Pricing Arrangements apply.						
2663E	Injection	360 mg	2	..	*47478.28	37.70	Yervoy (ipilimumab 200 mg/40 mL injection, 1 x 40 mL vial) BQ
							Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial) BQ

OFATUMUMAB

Authority required (STREAMLINED)

4858

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Chronic lymphocytic leukaemia (CLL)							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),							
	AND							
	Patient must have previously been issued with an authority prescription for this drug,							
	AND							
	Patient must not have progressive disease,							
	AND							
	Patient must be inappropriate for fludarabine based therapy,							
	AND							
	The treatment must be in combination with chlorambucil.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
10236R	Injection	1000 mg	5	..	*3487.71	37.70	Arzerra (ofatumumab 1 g/50 mL injection, 50 mL vial)	GK
<hr/>								
	OFATUMUMAB							
	Authority required (STREAMLINED)							
	<i>4828</i>							
	Chronic lymphocytic leukaemia (CLL)							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),							
	AND							
	The condition must be previously untreated,							
	AND							
	The treatment must be in combination with chlorambucil,							
	AND							
	Patient must be inappropriate for fludarabine based therapy.							
	Note							
	An initial dose of 1300 mg of PBS-subsidised ofatumumab must be made up of 3 vials of 100 mg and 1 vial of 1000 mg.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
10249K	Injection	300 mg	*1117.80	37.70	Arzerra (ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials)	GK
10252N	Injection	1000 mg	5	..	*3487.71	37.70	Arzerra (ofatumumab 1 g/50 mL injection, 50 mL vial)	GK

PANITUMUMAB

Authority required (STREAMLINED)

4784

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have RAS wild-type metastatic colorectal cancer,

AND

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Patient must have a WHO performance status of 2 or less,

AND

The condition must have failed to respond to first-line chemotherapy,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with an irinotecan based therapy,

AND

The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.

Authority required (STREAMLINED)

4783

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy,

AND

Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with an irinotecan based therapy,

AND

The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.

Note

Special Pricing Arrangements apply.

Note

Panitumumab is not PBS-subsidised for use in combination with oxaliplatin-based therapies.

10082P	Injection	720 mg	5	..	*5926.12	37.70	Vectibix (panitumumab 100 mg/5 mL injection, 1 x 5 mL vial)	AN
							Vectibix (panitumumab 400 mg/20 mL injection, 1 x 20 mL vial)	AN

RITUXIMAB

Authority required (STREAMLINED)

4674

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

Patient must have demonstrated a partial or complete response to the induction phase of treatment for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application,

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	AND						
	The treatment must be maintenance therapy,						
	AND						
	Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.						
	Note						
	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Special Pricing Arrangements apply.						
10179R	Injection	800 mg	11	..	*3354.80	37.70	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)

4701

Previously untreated CD20 positive diffuse large B-cell non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with chemotherapy,

AND

The condition must be previously untreated,

AND

The condition must be symptomatic,

AND

The treatment must be for induction treatment purposes only,

AND

Patient must not receive more than 8 doses under this restriction.

Authority required (STREAMLINED)

4726

Previously untreated Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with chemotherapy,

AND

The condition must be previously untreated,

AND

The condition must be symptomatic,

AND

The treatment must be for induction treatment purposes only,

AND

Patient must not receive more than 8 doses under this restriction.

Note

A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Authority required (STREAMLINED)

4686

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Treatment Phase: Maintenance therapy							
Clinical criteria:							
The treatment must be maintenance therapy,							
AND							
Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application,							
AND							
Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.							
Note							
No increase in the maximum number of repeats may be authorised.							
Note							
Special Pricing Arrangements apply.							
4613T	Injection	800 mg	7	..	*3354.80	37.70	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
<hr/>							
RITUXIMAB							
<u>Authority required (STREAMLINED)</u>							
4677							
Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma							
Treatment Phase: Re-induction treatment							
Clinical criteria:							
The treatment must be for re-induction treatment purposes only,							
AND							
The condition must have relapsed or be refractory to treatment,							
AND							
Patient must not receive more than 4 doses under this restriction.							
<u>Authority required (STREAMLINED)</u>							
4678							
Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma							
Treatment Phase: Re-induction treatment							
Clinical criteria:							
The treatment must be for re-induction treatment purposes only,							
AND							
The condition must have relapsed or be refractory to treatment,							
AND							
Patient must not receive more than 4 doses under this restriction.							
Note							
No increase in the maximum number of repeats may be authorised.							
4614W	Injection	800 mg	3	..	*3354.80	37.70	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
<hr/>							
RITUXIMAB							
<u>Authority required (STREAMLINED)</u>							
4706							
Chronic lymphocytic leukaemia (CLL)							
Clinical criteria:							
The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),							
AND							
The treatment must be in combination with chemotherapy.							

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Note							
This drug is not PBS-subsidised for use as monotherapy.							
Note							
No increase in the maximum number of repeats may be authorised.							
4615X	Injection	1100 mg	5	..	*4574.53	37.70	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)

Clinical criteria:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

AND

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

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)

Clinical criteria:

Patient must commence treatment concurrently with adjuvant chemotherapy,

AND

Patient must have undergone surgery,

AND

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

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.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
4632T	Injection	500 mg	*3604.81	37.70	Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) RO Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) RO

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

TRASTUZUMAB

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

Clinical criteria:

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

AND

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

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)

Clinical criteria:

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

AND

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

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).

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand 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							
4639E	Injection	250 mg	9	..	*1956.49	37.70	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)

Clinical criteria:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

AND

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

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)

Clinical criteria:

Patient must commence treatment concurrently with adjuvant chemotherapy,

AND

Patient must have undergone surgery,

AND

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

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.

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	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	*7107.48	37.70	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: Continuing treatment (3 weekly regimen)

Clinical criteria:

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

AND

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

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)

Clinical criteria:

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

AND

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

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

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	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	..	*5253.13	37.70	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)

4793

Acute promyelocytic leukaemia

Treatment Phase: Induction and consolidation treatment

Clinical criteria:

The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript,

AND

The condition must be relapsed,

AND

Patient must be arsenic naive at induction.

4371C	Injection	18 mg	89	..	*903.78	37.70	Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) PL
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BORTEZOMIB

Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

Patient must be newly diagnosed,

AND

Patient must be ineligible for high dose chemotherapy,

AND

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

AND

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

AND

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

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Clinical criteria:							
Patient must be newly diagnosed,							
AND							
Patient must have severe acute renal failure,							
AND							
Patient must require dialysis; OR							
Patient must be at high risk of requiring dialysis in the opinion of a nephrologist,							
AND							
The treatment must be in combination with a corticosteroid and/or cyclophosphamide,							
AND							
Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,							
AND							
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	..	*1571.25	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) JC

Chemotherapy Items for Public Hospital use

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

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

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

AND

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

AND

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

AND

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

AND

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

AND

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

Clinical criteria:

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

AND

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

AND

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

AND

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

AND

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.

Chemotherapy Items for Public Hospital use

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

4429D	Injection	3000 mcg	19	..	*1571.25	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
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BORTEZOMIB

Authority required

Multiple myeloma

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

Clinical criteria:

The condition must be confirmed by a histological diagnosis,

AND

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND

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:

Chemotherapy Items for Public Hospital use

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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

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

AND

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).

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
4706Q	Injection	3000 mcg	15	..	*1816.12	37.70	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC

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.

BORTEZOMIB

Authority required

Multiple myeloma

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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

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

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

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(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.						
4712B	Injection	3000 mcg	11	..	*1816.12	37.70	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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

Patient must have progressive disease,

AND

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

AND

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

AND

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

AND

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

Chemotherapy Items for Public Hospital use

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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

AND

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

AND

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Patient must not have a gap of more than 6 months between the initial application and subsequent applications,

AND

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	..	*1816.12	37.70	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial)	JC
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BORTEZOMIB

Authority required

Multiple myeloma

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

Clinical criteria:

The treatment must be as monotherapy; OR

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

AND

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

AND

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

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	AND						
	Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,						
	AND						
	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						
	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	..	*1816.12	37.70	Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC

BORTEZOMIB

Authority required

Symptomatic multiple myeloma

Clinical criteria:

Patient must be newly diagnosed,

AND

Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation,

AND

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

AND

The treatment must be in combination with chemotherapy,

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AND								
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	..	*1571.25	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
ERIBULIN								
Authority required (STREAMLINED)								
4649								
Locally advanced or metastatic breast cancer								
Clinical criteria:								
Patient must have progressive disease,								
AND								
Patient must have failed at least two prior chemotherapeutic regimens for this condition,								
AND								
The treatment must be the sole PBS-subsidised therapy for this condition.								
Note								
A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.								
Note								
Special Pricing Arrangements apply.								
10144X	Injection	3 mg	13	..	*1452.12	37.70	Halaven (eribulin mesilate 1 mg/2 mL injection, 1 x 2 mL vial)	EI
IRINOTECAN								
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	..	*197.58	37.70	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)	GN
							Irinoccord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	GN

Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)	UA
							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 MYX (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	YN
							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 500 mg/25 mL injection, 1 x 25 mL vial)	GN

TOPOTECAN

Authority required (STREAMLINED)

3186

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

4617B	Injection	3500 mcg	17	..	*166.65	37.70	Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials)	GK
							Topotecan Agila (topotecan 4 mg injection, 1 x 4 mg vial)	AF
							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

**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
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ALIMENTARY TRACT AND METABOLISM

ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS

Serotonin (5HT3) antagonists

GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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	*18.58	19.73	Kytril	RO
5899L	granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule	1	3.98	5.13	^a Granisetron Kabi	PK
							^a Granisetron-AFT	AE
							^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	37.70	Zofran syrup 50 mL	AS
5967C	ondansetron 4 mg tablet, 4	1	6.50	7.65	^a APO-Ondansetron	TX
							^a Ondansetron AN	EA
							^a Ondansetron-DRLA	RZ
							^a Ondaz	SZ
							^a Onsetron 4	ZP
							^a Zofran	AS
5968D	ondansetron 8 mg tablet, 4	1	10.18	11.33	^a APO-Ondansetron	TX
							^a Ondansetron AN	EA
							^a Ondansetron-DRLA	RZ
							^a Ondaz	SZ
							^a Onsetron 8	ZP
							^a Zofran	AS
5971G	ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	159	1.74	^a Ondansetron Alphapharm	AF
							^a Ondansetron Kabi	PK
							^a Ondansetron-Claris	AE
							^a Ondaz	SZ
							^a Onsetron	ZP
5972H	ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	194	2.09	^a Ondansetron Alphapharm	AF
							^a Ondansetron Kabi	PK
							^a Ondansetron-Claris	AE
							^a Ondaz	SZ
							^a Onsetron	ZP

ONDANSETRON

Restricted benefit

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
	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) 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	6.50	7.65	^a Ondansetron AN ODT EA
							^a Ondansetron ODT-DRLA RZ
							^a Ondansetron ODT 4 GN
5969E	ondansetron 4 mg wafer, 4	1	6.50	7.65	^a Ondaz Zydis SZ
							^a Zofran Zydis AS

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.

5858H	ONDANSETRON Tablet (orally disintegrating) 8 mg, 4	1	10.18	11.33	^a Ondansetron AN ODT EA
							^a Ondansetron ODT-DRLA RZ
							^a Ondansetron ODT 8 GN
5970F	ondansetron 8 mg wafer, 4	1	10.18	11.33	^a Ondaz Zydis SZ
							^a Zofran Zydis AS

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.

5853C	palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial	1	34.36	35.51	Aloxi TS
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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

5987D	tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule	1	5.88	7.03	Tropisetron-AFT AE
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Other antiemetics

APREPITANT

Authority required (STREAMLINED)

4223

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,

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
	AND						
	Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.						
	No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.						
	<u>Authority required (STREAMLINED)</u>						
	4216						
	Nausea and vomiting						
	Clinical criteria:						
	The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer,						
	AND						
	The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,						
	AND						
	Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.						
	No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.						
	<u>Authority required (STREAMLINED)</u>						
	4217						
	Nausea and vomiting						
	Clinical criteria:						
	The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy,						
	AND						
	The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle,						
	AND						
	Patient must have had a prior episode of chemotherapy induced nausea or vomiting,						
	AND						
	Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; carboplatin; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; oxaliplatin; raltitrexed.						
	No more than 1 capsule of aprepitant 165 mg 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.						
	<u>Note</u>						
	Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
2550F	aprepitant 165 mg capsule, 1	1	5	..	111.08	37.70	Emend MK

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
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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	37.70	Roferon-A	RO
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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	37.70	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	37.70	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	37.70	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	37.70	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	37.70	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	37.70	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	37.70	Roferon-A	RO

INTERFERON ALFA-2B

Caution

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	
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.								
<u>Authority required (STREAMLINED)</u>								
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	37.70	Intron A Redipen	MK
INTERFERON ALFA-2B								
<u>Caution</u>								
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.								
<u>Authority required (STREAMLINED)</u>								
3898								
Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy								
<u>Authority required (STREAMLINED)</u>								
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	37.70	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	37.70	Intron A Redipen	MK
<i>Other immunostimulants</i>								
BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN								
<u>Restricted benefit</u>								
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	37.70	ImmuCyst	SW
BACILLUS CALMETTE AND GUERIN-TICE STRAIN								
<u>Restricted benefit</u>								
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	37.70	OncoTICE	MK

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 \$	a	Brand Name and Manufacturer	
VARIOUS									
ALL OTHER THERAPEUTIC PRODUCTS									
ALL OTHER THERAPEUTIC PRODUCTS									
<i>Detoxifying agents for antineoplastic treatment</i>									
FOLINIC ACID									
Note									
For item codes 5890B 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	..	43.80	37.70	a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
<hr/>									
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	..	40.50	37.70	a	Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
<hr/>									
FOLINIC ACID									
5863N	folinic acid 1 g/100 mL injection, 1 x 100 mL vial	1	1	..	40.47	37.70		Calcium Folate Ebewe	SZ
5870Y	folinic acid 300 mg/30 mL injection, 1 x 30 mL vial	4	1	..	*47.36	37.70	a	Calcium Folate Ebewe	SZ
							a	Leucovorin Calcium (Hospira Pty Limited)	HH
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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	..	*40.50	37.70	a	Calcium Folate Ebewe	SZ
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FOLINIC ACID									
Note									
For item codes 5890B 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	..	*43.80	37.70	a	Leucovorin Calcium (Hospira Pty Limited)	HH
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FOLINIC ACID									
Restricted benefit									
Antidote to folic acid antagonists									
5904R	folinic acid 15 mg tablet, 10	1	76.00	37.70		Leucovorin Calcium (Hospira Pty Limited)	HH
<hr/>									
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	37.70		Uromitexan	BX

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	
5961R	mesna 1 g/10 mL injection, 15 x 10 mL ampoules	1	5	..	185.44	37.70	Uromitexan	BX

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<i>Hospira Pty Limited (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) (HH)</i>	
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<i>Hospira Pty Limited (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>	
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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	44, 82
<i>Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>	
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<i>Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) (HH)</i>	
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<i>Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	11, 49
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<i>Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial) (HH)</i>	
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<i>Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials) (HH)</i>	
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<i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (AF)</i>	
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<i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
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<i>Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial) (JC)</i>	
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<i>Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	17, 55
<i>Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial) (OA)</i>	
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<i>Methotrexate MYX (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (YN)</i>	
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<i>Methotrexate MYX (METHOTREXATE Injection 50 mg in 2 mL, 1) (YN)</i>	
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<i>Mitozantrone Ebewe (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (SZ)</i>	
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<i>Oxaliplatin SUN (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (ZF)</i>	
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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Paclitaxel Kabi (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Paclitaxel Kabi (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (PK)</i>	
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PACLITAXEL NANOPARTICLE ALBUMIN BOUND	
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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	26, 64
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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	12, 50
<i>Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials) (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	13, 51
<i>Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) (PL)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	34, 72
<i>Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	16, 54
<i>Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (GN)</i>	
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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	12, 50

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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	89

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<i>Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	15, 53
<i>Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) (SW)</i>	
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<i>Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	45, 83
<i>Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial) (HH)</i>	
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<i>Topotecan Agila (topotecan 4 mg injection, 1 x 4 mg vial) (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	45, 83
<i>Topotecan Kabi (topotecan 4 mg injection, 5 x 4 mg vials) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	45, 83
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<i>Vectibix (panitumumab 100 mg/5 mL injection, 1 x 5 mL vial) (AN)</i>	
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<i>Vectibix (panitumumab 400 mg/20 mL injection, 1 x 20 mL vial) (AN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	27, 65
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<i>Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) (JC)</i>	
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<i>Vinorelbine Ebewe (vinorelbine 10 mg/mL injection, 1 x 1 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	14, 52
<i>Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	14, 52
<i>Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (PK)</i>	
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<i>Yervoy (ipilimumab 200 mg/40 mL injection, 1 x 40 mL vial) (BQ)</i>	
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<i>Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial) (BQ)</i>	
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Z

<i>Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6) (PF)</i>	
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<i>Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3) (PF)</i>	
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