



**Australian Government**

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**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](http://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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# Contents

Summary of Changes .....	4
Efficient Funding of Chemotherapy (Public Hospital).....	4
Alterations.....	4
Efficient Funding of Chemotherapy (Private Hospital) .....	5
Alterations.....	5
EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS .....	6
Explanatory Notes.....	6
Section 100 cancer chemotherapy drugs .....	6
Prescribing and Supplying - Information for PBS Prescribers and Pharmacists .....	6
Authorisation requirements .....	7
Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines .....	7
Remuneration arrangements .....	7
THERAPEUTIC INDEX .....	9
CHEMOTHERAPY ITEMS FOR PRIVATE HOSPITAL/PRIVATE CLINIC USE .....	11
CHEMOTHERAPY ITEMS FOR PUBLIC HOSPITAL USE.....	49
Related Pharmaceutical Benefits (not subject to the revised arrangements) for Public Hospital use.....	87
GENERIC/PROPRIETARY INDEX .....	95

## Summary of Changes

### Efficient Funding of Chemotherapy (Public Hospital)

#### Alterations

##### *Alteration – Restriction*

10115J **BEVACIZUMAB,**  
 bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial (*Avastin*);  
 bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial (*Avastin*)

##### *Alteration – Restriction Level*

		<i>From</i>	<i>To</i>
4620E	<b>VINOURELBINE,</b> vinorelbine 10 mg/mL injection, 1 x 1 mL vial ( <i>Vinorelbine Ebewe</i> ); vinorelbine 10 mg/mL injection, 1 x 1 mL vial ( <i>Navelbine</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Navelbine</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Vinorelbine Ebewe</i> ); vinorelbine 10 mg/mL injection, 1 x 1 mL vial ( <i>Hospira Pty Limited</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Hospira Pty Limited</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Vinorelbine Kabi</i> )	streamlined	unrestricted

## Efficient Funding of Chemotherapy (Private Hospital)

### Alterations

#### *Alteration – Restriction*

10120P **BEVACIZUMAB,**  
 bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial (*Avastin*);  
 bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial (*Avastin*)

#### *Alteration – Restriction Level*

		<i>From</i>	<i>To</i>
7263G	<b>VINORELBINE,</b> vinorelbine 10 mg/mL injection, 1 x 1 mL vial ( <i>Vinorelbine Ebewe</i> ); vinorelbine 10 mg/mL injection, 1 x 1 mL vial ( <i>Navelbine</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Navelbine</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Vinorelbine Ebewe</i> ); vinorelbine 10 mg/mL injection, 1 x 1 mL vial ( <i>Hospira Pty Limited</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Hospira Pty Limited</i> ); vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial ( <i>Vinorelbine Kabi</i> )	streamlined	unrestricted

# 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<sup>®</sup>), 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](http://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](http://www.pbs.gov.au) or the Department of Human Services' website at [www.humanservices.gov.au](http://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](http://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)



# THERAPEUTIC INDEX

<b>CHEMOTHERAPY ITEMS FOR PRIVATE HOSPITAL/PRIVATE CLINIC USE.....</b>	<b>11</b>
<b>ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....</b>	<b>13</b>
ANTINEOPLASTIC AGENTS .....	13
ALKYLATING AGENTS .....	13
ANTIMETABOLITES.....	13
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS .....	16
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES .....	19
OTHER ANTINEOPLASTIC AGENTS .....	20
<b>CHEMOTHERAPY ITEMS FOR PUBLIC HOSPITAL USE .....</b>	<b>49</b>
<b>ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....</b>	<b>51</b>
ANTINEOPLASTIC AGENTS .....	51
ALKYLATING AGENTS .....	51
ANTIMETABOLITES.....	51
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS .....	54
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES .....	57
OTHER ANTINEOPLASTIC AGENTS .....	58
<b>Related Pharmaceutical Benefits (not subject to the revised arrangements) for Public Hospital use.....</b>	<b>87</b>
<b>ALIMENTARY TRACT AND METABOLISM .....</b>	<b>88</b>
ANTIEMETICS AND ANTINAUSEANTS .....	88
ANTIEMETICS AND ANTINAUSEANTS.....	88
<b>ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....</b>	<b>91</b>
IMMUNOSTIMULANTS .....	91
IMMUNOSTIMULANTS.....	91
<b>VARIOUS.....</b>	<b>93</b>
ALL OTHER THERAPEUTIC PRODUCTS.....	93
ALL OTHER THERAPEUTIC PRODUCTS.....	93



**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	<sup>s</sup> 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	..	*153.09	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 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							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	..	..	*1147.86	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

## 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	
							mL injection, 1 x 20 mL vial)	
							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 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							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

#### **Authority required (STREAMLINED)**

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

#### **Authority required (STREAMLINED)**

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

#### **Authority required (STREAMLINED)**

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
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### ***Purine analogues***

#### CLADRIBINE

#### **Authority required (STREAMLINED)**

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

#### **Authority required (STREAMLINED)**

3887

B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

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

(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and

## 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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(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

### **Note**

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

7233Q	Injection	55 mg	29	..	*241.36	37.70	Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	GN
							Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)	GZ
							Fludarabine ACT (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	VN
							Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	UA
							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
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#### **FLUOROURACIL**

##### **Restricted benefit**

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
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH

#### **FLUOROURACIL**

##### **Restricted benefit**

For patients requiring administration of fluorouracil by intravenous injection.

7239B	Injection	1000 mg	23	..	*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
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH

#### **GEMCITABINE**

##### **Caution**

Pharmaceutical benefits containing gemcitabine may have different concentrations.

##### **Note**

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

##### **Note**

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

### **Note**

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

7246J	Injection	3000 mg	17	..	*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
							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*

<b>VINBLASTINE</b>								
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
<b>VINCRIStINE</b>								
7262F	Injection	2 mg	7	..	*159.66	37.70	Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)	HH
<b>VINORELBINE</b>								
7263G	Injection	70 mg	7	..	*224.95	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

## 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	
							Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	PK
<b>Podophyllotoxin derivatives</b>								
<b>ETOPOSIDE</b>								
7237X	Injection	440 mg	14	..	*222.34	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
<b>Taxanes</b>								
<b>CABAZITAXEL</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4662</b>								
Castration resistant metastatic carcinoma of the prostate								
<b>Clinical criteria:</b>								
The treatment must be in combination with prednisone or prednisolone,								
<b>AND</b>								
The treatment must not be used in combination with abiraterone,								
<b>AND</b>								
Patient must have failed treatment with docetaxel due to resistance or intolerance,								
<b>AND</b>								
Patient must have a WHO performance status of 2 or less,								
<b>AND</b>								
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.								
<b><u>Note</u></b>								
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
<b>DOCETAXEL</b>								
<b><u>Note</u></b>								
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	..	*237.54	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 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	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
<b>PACLITAXEL</b>								
7254T	Injection	450 mg	3	..	*214.71	37.70	Anzatax (paclitaxel 100 mg/16.7 mL injection, 1	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	
							x 16.7 mL vial)	
							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
							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 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)	SZ
							Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Paclitaxel Kabi (paclitaxel 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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## 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
<b>CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES</b>							
<b><i>Anthracyclines and related substances</i></b>							
<b>DOXORUBICIN</b>							
7229L	Injection/intravenous	135 mg	11	..	*177.77	37.70	Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) GN
							Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) GN
							Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) SZ
							Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) SZ
							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
							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
<b>DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL</b>							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4786</b>							
Advanced epithelial ovarian cancer							
<b>Clinical criteria:</b>							
Patient must have failed a first-line platinum-based chemotherapy regimen.							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4791</b>							
Metastatic breast cancer							
<b>Clinical criteria:</b>							
The treatment must be as monotherapy,							
<b>AND</b>							
Patient must have failed prior therapy which included capecitabine and a taxane.							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4787</b>							
Metastatic breast cancer							
<b>Clinical criteria:</b>							
The treatment must be as monotherapy,							
<b>AND</b>							
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
<b>EPIRUBICIN</b>							
7231N	Injection/intravenous	220 mg	5	..	*212.23	37.70	DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL) HH

## Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							injection, 1 x 100 mL vial)	
							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 Ebewe (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Epirubicin Kabi (epirubicin hydrochloride 200 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
<b>IDARUBICIN</b>								
<b><u>Restricted benefit</u></b>								
Acute myelogenous leukaemia								
7247K	Injection	30 mg	5	..	*602.79	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
<b>MITOZANTRONE</b>								
7252Q	Injection	30 mg	5	..	*319.48	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
<b>OTHER ANTINEOPLASTIC AGENTS</b>								
<b><i>Platinum compounds</i></b>								
<b>CARBOPLATIN</b>								
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

## 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	
<b>CISPLATIN</b>								
7224F	Injection	220 mg	14	..	*171.74	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	..	*200.81	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
							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
							Oxalliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	GN
							Oxalliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	GN
							Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial)	UA
							Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial)	UA
							Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial)	SZ
							Oxaliplatin Ebewe (oxaliplatin 50 mg injection, 1 x 50 mg vial)	SZ
							Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	PK
							Oxaliplatin 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

## 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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**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,

**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****Authority required (STREAMLINED)****4594**

Metastatic colorectal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

The condition must be previously untreated,

**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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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.

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

**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

## 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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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](http://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.

**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:**

## 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	
	The treatment must be in combination with radiotherapy,							
	<b>AND</b>							
	Patient must be unable to tolerate cisplatin.							
	<b>Note</b>							
	No increase in the maximum number of repeats may be authorised.							
7223E	Injection	880 mg	..	..	*3274.26	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
<hr/>								
	<b>CETUXIMAB</b>							
	<b><u>Authority required (STREAMLINED)</u></b>							
	<b>4788</b>							
	Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx							
	Treatment Phase: Continuing treatment							
	<b>Clinical criteria:</b>							
	The treatment must be in combination with radiotherapy,							
	<b>AND</b>							
	Patient must be unable to tolerate cisplatin; OR							
	Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.							
	<b>Note</b>							
	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	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
<hr/>								
	<b>CETUXIMAB</b>							
	<b><u>Authority required (STREAMLINED)</u></b>							
	<b>4779</b>							
	Metastatic colorectal cancer							
	Treatment Phase: Initial treatment							
	<b>Clinical criteria:</b>							
	Patient must have RAS wild-type metastatic colorectal cancer,							
	<b>AND</b>							
	Patient must have a WHO performance status of 2 or less,							
	<b>AND</b>							
	The condition must have failed to respond to first-line chemotherapy,							
	<b>AND</b>							
	The treatment must be as monotherapy; OR							
	The treatment must be in combination with an irinotecan based therapy,							
	<b>AND</b>							
	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.							
	<b>Note</b>							

## 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.

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**

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:

## 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
	<p>(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;</p> <p>(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.</p> <p><b><u>Authority required (STREAMLINED)</u></b>  <b>4261</b>            Unresectable Stage III or Stage IV malignant melanoma            Treatment Phase: Re-induction treatment</p> <p><b>Clinical criteria:</b>            The treatment must be as monotherapy,</p> <p><b>AND</b>            Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction),</p> <p><b>AND</b>            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:</p> <p>(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.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.</p> <p><b>Note</b>            No increase in the maximum number of repeats may be authorised.</p> <p><b>Note</b>            Special Pricing Arrangements apply.</p>						
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)**

**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**

## 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
	Unresectable Stage III or Stage IV malignant melanoma						
	Treatment Phase: Completion of re-induction treatment						
	<b>Clinical criteria:</b>						
	The treatment must be as monotherapy,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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).						
	<b>Note</b>						
	No increase in the maximum number of repeats may be authorised.						
	<b>Note</b>						
	A patient may only qualify for PBS-subsidised treatment under this restriction once.						
	<b>Note</b>						
	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) BQ
							Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial) BQ

### PANITUMUMAB

#### **Authority required (STREAMLINED)**

4784

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 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.

## 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
	<b><u>Authority required (STREAMLINED)</u></b>						
	<b>4783</b>						
	Metastatic colorectal cancer						
	Treatment Phase: Continuing treatment						
	<b>Clinical criteria:</b>						
	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,						
	<b>AND</b>						
	Patient must not have progressive disease,						
	<b>AND</b>						
	The treatment must be as monotherapy; OR						
	The treatment must be in combination with an irinotecan based therapy,						
	<b>AND</b>						
	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.						
	<b><u>Note</u></b>						
	Special Pricing Arrangements apply.						
	<b><u>Note</u></b>						
	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
	<b>RITUXIMAB</b>						
	<b><u>Authority required (STREAMLINED)</u></b>						
	<b>4674</b>						
	Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma						
	Treatment Phase: Maintenance therapy						
	<b>Clinical criteria:</b>						
	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,						
	<b>AND</b>						
	The treatment must be maintenance therapy,						
	<b>AND</b>						
	Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.						
	<b><u>Note</u></b>						
	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.						
	<b><u>Note</u></b>						
	No increase in the maximum number of repeats may be authorised.						
	<b><u>Note</u></b>						
	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

## 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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### 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,

**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,

## 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
	<b>AND</b>						
	The condition must be symptomatic,						
	<b>AND</b>						
	The treatment must be for induction treatment purposes only,						
	<b>AND</b>						
	Patient must not receive more than 8 doses under this restriction.						
	<b>Note</b>						
	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.						
	<b>Authority required (STREAMLINED)</b>						
	<b>4686</b>						
	Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma						
	Treatment Phase: Maintenance therapy						
	<b>Clinical criteria:</b>						
	The treatment must be maintenance therapy,						
	<b>AND</b>						
	Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application,						
	<b>AND</b>						
	Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.						
	<b>Note</b>						
	No increase in the maximum number of repeats may be authorised.						
	<b>Note</b>						
	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
	<b>RITUXIMAB</b>						
	<b>Authority required (STREAMLINED)</b>						
	<b>4706</b>						
	Chronic lymphocytic leukaemia (CLL)						
	<b>Clinical criteria:</b>						
	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL),						
	<b>AND</b>						
	The treatment must be in combination with chemotherapy.						
	<b>Note</b>						
	This drug is not PBS-subsidised for use as monotherapy.						
	<b>Note</b>						
	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
	<b>TRASTUZUMAB</b>						
	<b>Authority required</b>						
	Locally advanced HER2 positive breast cancer						
	Treatment Phase: Initial treatment (weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with neoadjuvant chemotherapy,						

## Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b>Authority required</b>						
	Early HER2 positive breast cancer						
	Treatment Phase: Initial treatment (weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with adjuvant chemotherapy,						
	<b>AND</b>						
	Patient must have undergone surgery,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b>Note</b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	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

## 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
<b>TRASTUZUMAB</b>							
<b><u>Authority required</u></b>							
Locally advanced HER2 positive breast cancer							
Treatment Phase: Continuing treatment (weekly regimen)							
<b>Clinical criteria:</b>							
Patient must have previously received treatment with PBS-subsidised trastuzumab,							
<b>AND</b>							
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,							
<b>AND</b>							
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.							
<b><u>Authority required</u></b>							
Early HER2 positive breast cancer							
Treatment Phase: Continuing treatment (weekly regimen)							
<b>Clinical criteria:</b>							
Patient must have previously received treatment with PBS-subsidised trastuzumab,							
<b>AND</b>							
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,							
<b>AND</b>							
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.							
<b><u>Note</u></b>							
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).							
<b><u>Note</u></b>							
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).							
<b><u>Note</u></b>							
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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>							
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**

## 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
	Locally advanced HER2 positive breast cancer						
	Treatment Phase: Initial treatment (3 weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with neoadjuvant chemotherapy,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b><u>Authority required</u></b>						
	Early HER2 positive breast cancer						
	Treatment Phase: Initial treatment (3 weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with adjuvant chemotherapy,						
	<b>AND</b>						
	Patient must have undergone surgery,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b><u>Note</u></b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	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						

## 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	
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).

#### 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](http://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

## 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 vial)
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### ***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**

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.

## 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 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](http://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
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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,

## 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**

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.

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

## 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
<b>Clinical criteria:</b>							
The treatment must be as monotherapy; OR							
The treatment must be in combination with a corticosteroid and/or cyclophosphamide,							
<b>AND</b>							
Patient must have previously received 4 treatment cycles of bortezomib for progressive disease,							
<b>AND</b>							
Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib,							
<b>AND</b>							
Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,							
<b>AND</b>							
Patient must not have a gap of more than 6 months between the initial application and subsequent applications,							
<b>AND</b>							
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.							
<b>Note</b>							
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.							
<b>Note</b>							
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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>							
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							
<b>Note</b>							
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

## 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
	<b><u>Authority required</u></b>						
	Multiple myeloma						
	Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment						
	<b>Clinical criteria:</b>						
	The treatment must be as monotherapy; OR						
	The treatment must be in combination with a corticosteroid and/or cyclophosphamide,						
	<b>AND</b>						
	Patient must have previously received 8 treatment cycles of bortezomib for progressive disease,						
	<b>AND</b>						
	Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib,						
	<b>AND</b>						
	Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,						
	<b>AND</b>						
	Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles,						
	<b>AND</b>						
	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.						
	<b><u>Note</u></b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	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						
	<b><u>Note</u></b>						
	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

## 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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### **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
- (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

## 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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(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
- (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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

## 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
	Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	<b>Note</b> 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:

- (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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

## 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
	Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	<b>Note</b> 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

### **BOREZOMIB**

#### **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.

## 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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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](http://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,

**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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

## 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	
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	<b>Note</b>							
	Special Pricing Arrangements apply.							
7275X	Injection	3000 mcg	15	..	*1667.04	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
	<b>ERIBULIN</b>							
	<b>Authority required</b>							
	Locally advanced or metastatic breast cancer							
	<b>Clinical criteria:</b>							
	Patient must have progressive disease,							
	<b>AND</b>							
	Patient must have failed at least two prior chemotherapeutic regimens for this condition,							
	<b>AND</b>							
	The treatment must be the sole PBS-subsidised therapy for this condition.							
	<b>Note</b>							
	A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.							
	<b>Note</b>							
	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
	<b>IRINOTECAN</b>							
	<b>Note</b>							
	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	..	*258.45	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
							Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	UA
							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 100 mg/5 mL injection, 1 x 5 mL vial)	SZ

## Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)	
							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 100 mg/5 mL injection, 1 x 5 mL vial)	GN
							Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	GN
							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	..	*265.59	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	<sup>s</sup> 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	..	*114.27	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 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							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	..	..	*1072.04	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

## 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	
							mL injection, 1 x 20 mL vial)	
							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 1 g/10 mL injection, 1 x 10 mL vial)	SZ
							Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)	SZ
							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

#### **Authority required (STREAMLINED)**

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

#### **Authority required (STREAMLINED)**

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

#### **Authority required (STREAMLINED)**

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
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### *Purine analogues*

#### CLADRIBINE

#### **Authority required (STREAMLINED)**

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

#### **Authority required (STREAMLINED)**

3887

B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

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

(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and

## 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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(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

### **Note**

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

4393F	Injection	55 mg	29	..	*195.04	37.70	Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	GN
							Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)	GZ
							Fludarabine ACT (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	VN
							Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)	UA
							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
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#### **FLUOROURACIL**

##### **Restricted benefit**

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
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH

#### **FLUOROURACIL**

##### **Restricted benefit**

For patients requiring administration of fluorouracil by intravenous injection.

4431F	Injection	1000 mg	23	..	*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
							Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	SZ
							Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)	HH

#### **GEMCITABINE**

##### **Caution**

Pharmaceutical benefits containing gemcitabine may have different concentrations.

##### **Note**

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

##### **Note**

## 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	
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.								
<b>Note</b>								
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/5.3 mL injection, 1 x 5.3 mL vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 1 g injection, 1 x 1 g vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 2 g injection, 1 x 2 g vial)	HH
							DBL Gemcitabine for Injection (gemcitabine 200 mg injection, 1 x 200 mg vial)	HH
							Gemaccord (gemcitabine 1 g injection, 1 x 1 g vial)	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*

<b>VINBLASTINE</b>								
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
<b>VINCRIStINE</b>								
4619D	Injection	2 mg	7	..	*119.96	37.70	Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)	HH
<b>VINORELBINE</b>								
4620E	Injection	70 mg	7	..	*180.14	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

## 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	
							Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)	PK
<b>Podophyllotoxin derivatives</b>								
<b>ETOPOSIDE</b>								
4428C	Injection	440 mg	14	..	*177.77	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
<b>Taxanes</b>								
<b>CABAZITAXEL</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4662</b>								
Castration resistant metastatic carcinoma of the prostate								
<b>Clinical criteria:</b>								
The treatment must be in combination with prednisone or prednisolone,								
<b>AND</b>								
The treatment must not be used in combination with abiraterone,								
<b>AND</b>								
Patient must have failed treatment with docetaxel due to resistance or intolerance,								
<b>AND</b>								
Patient must have a WHO performance status of 2 or less,								
<b>AND</b>								
Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.								
<b><u>Note</u></b>								
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
<b>DOCETAXEL</b>								
<b><u>Note</u></b>								
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	..	*191.57	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 20 mg/2 mL injection, 1 x 2 mL vial)	SZ
							Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)	SZ
							Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)	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
<b>PACLITAXEL</b>								
4567J	Injection	450 mg	3	..	*170.82	37.70	Anzatax (paclitaxel 100 mg/16.7 mL injection, 1	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	
							x 16.7 mL vial)	
							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
							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 100 mg/16.7 mL injection, 1 x 16.7 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)	SZ
							Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Paclitaxel Kabi (paclitaxel 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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## 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
<b>CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES</b>							
<b><i>Anthracyclines and related substances</i></b>							
<b>DOXORUBICIN</b>							
4361M	Injection/intravesical	135 mg	11	..	*137.10	37.70	Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) GN Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) GN Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) SZ Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) SZ Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) SZ Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) SZ 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 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
<b>DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL</b>							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4786</b>							
Advanced epithelial ovarian cancer							
<b>Clinical criteria:</b>							
Patient must have failed a first-line platinum-based chemotherapy regimen.							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4791</b>							
Metastatic breast cancer							
<b>Clinical criteria:</b>							
The treatment must be as monotherapy,							
<b>AND</b>							
Patient must have failed prior therapy which included capecitabine and a taxane.							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4787</b>							
Metastatic breast cancer							
<b>Clinical criteria:</b>							
The treatment must be as monotherapy,							
<b>AND</b>							
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
<b>EPIRUBICIN</b>							
4375G	Injection/intravesical	220 mg	5	..	*168.56	37.70	DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL) HH

## Chemotherapy Items for Public Hospital use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							injection, 1 x 100 mL vial)	
							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 Ebewe (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)	SZ
							Epirubicin Ebewe (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)	SZ
							Epirubicin Kabi (epirubicin hydrochloride 200 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
<b>IDARUBICIN</b>								
<b><u>Restricted benefit</u></b>								
Acute myelogenous leukaemia								
4440Q	Injection	30 mg	5	..	*547.77	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
<b>MITOZANTRONE</b>								
4514N	Injection	30 mg	5	..	*266.06	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
<b>OTHER ANTINEOPLASTIC AGENTS</b>								
<b><i>Platinum compounds</i></b>								
<b>CARBOPLATIN</b>								
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

## 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	
<b>CISPLATIN</b>								
4319H	Injection	220 mg	14	..	*130.47	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.

4542C	Injection	300 mg	11	..	*158.19	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
							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
							Oxalliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	GN
							Oxalliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)	GN
							Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial)	UA
							Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial)	UA
							Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial)	SZ
							Oxaliplatin Ebewe (oxaliplatin 50 mg injection, 1 x 50 mg vial)	SZ
							Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)	PK
							Oxaliplatin 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

## 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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**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:**

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**

## 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 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**

**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

## 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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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](http://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**

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
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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:**

## 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	
	The treatment must be in combination with radiotherapy,							
	<b>AND</b>							
	Patient must be unable to tolerate cisplatin.							
	<b>Note</b>							
	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
<hr/>								
	<b>CETUXIMAB</b>							
	<b>Authority required (STREAMLINED)</b>							
	<b>4788</b>							
	Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx							
	Treatment Phase: Continuing treatment							
	<b>Clinical criteria:</b>							
	The treatment must be in combination with radiotherapy,							
	<b>AND</b>							
	Patient must be unable to tolerate cisplatin; OR							
	Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.							
	<b>Note</b>							
	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
<hr/>								
	<b>CETUXIMAB</b>							
	<b>Authority required (STREAMLINED)</b>							
	<b>4779</b>							
	Metastatic colorectal cancer							
	Treatment Phase: Initial treatment							
	<b>Clinical criteria:</b>							
	Patient must have RAS wild-type metastatic colorectal cancer,							
	<b>AND</b>							
	Patient must have a WHO performance status of 2 or less,							
	<b>AND</b>							
	The condition must have failed to respond to first-line chemotherapy,							
	<b>AND</b>							
	The treatment must be as monotherapy; OR							
	The treatment must be in combination with an irinotecan based therapy,							
	<b>AND</b>							
	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.							
	<b>Note</b>							

## 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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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.

**Note**

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

4731B	Injection	550 mg	11	..	*2148.12	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

**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:

## 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
	<p>(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;</p> <p>(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.</p> <p><b><u>Authority required (STREAMLINED)</u></b>  <b>4261</b>            Unresectable Stage III or Stage IV malignant melanoma            Treatment Phase: Re-induction treatment</p> <p><b>Clinical criteria:</b>            The treatment must be as monotherapy,</p> <p><b>AND</b>            Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction),</p> <p><b>AND</b>            The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p> <p>An initial objective response to treatment is defined as either:</p> <p>(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</p> <p>(ii) a partial or complete response.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.</p> <p><b>Note</b>            No increase in the maximum number of repeats may be authorised.</p> <p><b>Note</b>            Special Pricing Arrangements apply.</p>						
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**

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**

## 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 re-induction treatment						
	<b>Clinical criteria:</b>						
	The treatment must be as monotherapy,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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).						
	<b>Note</b>						
	No increase in the maximum number of repeats may be authorised.						
	<b>Note</b>						
	A patient may only qualify for PBS-subsidised treatment under this restriction once.						
	<b>Note</b>						
	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

### PANITUMUMAB

#### **Authority required (STREAMLINED)**

4784

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 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.

## 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
<b><u>Authority required (STREAMLINED)</u></b>							
	<b>4783</b>	Metastatic colorectal cancer					
		Treatment Phase: Continuing treatment					
	<b>Clinical criteria:</b>						
	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,						
	<b>AND</b>						
	Patient must not have progressive disease,						
	<b>AND</b>						
	The treatment must be as monotherapy; OR						
	The treatment must be in combination with an irinotecan based therapy,						
	<b>AND</b>						
	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.						
	<b><u>Note</u></b>						
	Special Pricing Arrangements apply.						
	<b><u>Note</u></b>						
	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
<b>RITUXIMAB</b>							
<b><u>Authority required (STREAMLINED)</u></b>							
	<b>4674</b>	Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma					
		Treatment Phase: Maintenance therapy					
	<b>Clinical criteria:</b>						
	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,						
	<b>AND</b>						
	The treatment must be maintenance therapy,						
	<b>AND</b>						
	Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.						
	<b><u>Note</u></b>						
	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.						
	<b><u>Note</u></b>						
	No increase in the maximum number of repeats may be authorised.						
	<b><u>Note</u></b>						
	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

## 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
<b>RITUXIMAB</b>							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4701</b>							
Previously untreated CD20 positive diffuse large B-cell non-Hodgkin's lymphoma							
Treatment Phase: Induction treatment							
<b>Clinical criteria:</b>							
The treatment must be in combination with chemotherapy,							
<b>AND</b>							
The condition must be previously untreated,							
<b>AND</b>							
The condition must be symptomatic,							
<b>AND</b>							
The treatment must be for induction treatment purposes only,							
<b>AND</b>							
Patient must not receive more than 8 doses under this restriction.							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4726</b>							
Previously untreated Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma							
Treatment Phase: Induction treatment							
<b>Clinical criteria:</b>							
The treatment must be in combination with chemotherapy,							
<b>AND</b>							
The condition must be previously untreated,							
<b>AND</b>							
The condition must be symptomatic,							
<b>AND</b>							
The treatment must be for induction treatment purposes only,							
<b>AND</b>							
Patient must not receive more than 8 doses under this restriction.							
<b><u>Note</u></b>							
A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.							
<b><u>Authority required (STREAMLINED)</u></b>							
<b>4686</b>							
Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma							
Treatment Phase: Maintenance therapy							
<b>Clinical criteria:</b>							
The treatment must be maintenance therapy,							
<b>AND</b>							
Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application,							
<b>AND</b>							
Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.							
<b><u>Note</u></b>							
No increase in the maximum number of repeats may be authorised.							
<b><u>Note</u></b>							
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

## 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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### 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.

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

### RITUXIMAB

#### Authority required (STREAMLINED)

**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.

#### 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,

## 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
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b>Authority required</b>						
	Early HER2 positive breast cancer						
	Treatment Phase: Initial treatment (weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with adjuvant chemotherapy,						
	<b>AND</b>						
	Patient must have undergone surgery,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b>Note</b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
4632T	Injection	500 mg	..	..	*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

## 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
<b>TRASTUZUMAB</b>							
<b><u>Authority required</u></b>							
Locally advanced HER2 positive breast cancer							
Treatment Phase: Continuing treatment (weekly regimen)							
<b>Clinical criteria:</b>							
Patient must have previously received treatment with PBS-subsidised trastuzumab,							
<b>AND</b>							
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,							
<b>AND</b>							
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.							
<b><u>Authority required</u></b>							
Early HER2 positive breast cancer							
Treatment Phase: Continuing treatment (weekly regimen)							
<b>Clinical criteria:</b>							
Patient must have previously received treatment with PBS-subsidised trastuzumab,							
<b>AND</b>							
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,							
<b>AND</b>							
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.							
<b><u>Note</u></b>							
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).							
<b><u>Note</u></b>							
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).							
<b><u>Note</u></b>							
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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>							
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**

## 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
	Locally advanced HER2 positive breast cancer						
	Treatment Phase: Initial treatment (3 weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with neoadjuvant chemotherapy,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b><u>Authority required</u></b>						
	Early HER2 positive breast cancer						
	Treatment Phase: Initial treatment (3 weekly regimen)						
	<b>Clinical criteria:</b>						
	Patient must commence treatment concurrently with adjuvant chemotherapy,						
	<b>AND</b>						
	Patient must have undergone surgery,						
	<b>AND</b>						
	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,						
	<b>AND</b>						
	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.						
	<b><u>Note</u></b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	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						

## 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	
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
<b>TRASTUZUMAB</b>								
<b><u>Authority required</u></b>								
Locally advanced HER2 positive breast cancer								
Treatment Phase: Continuing treatment (3 weekly regimen)								
<b>Clinical criteria:</b>								
Patient must have previously received treatment with PBS-subsidised trastuzumab,								
<b>AND</b>								
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,								
<b>AND</b>								
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.								
<b><u>Authority required</u></b>								
Early HER2 positive breast cancer								
Treatment Phase: Continuing treatment (3 weekly regimen)								
<b>Clinical criteria:</b>								
Patient must have previously received treatment with PBS-subsidised trastuzumab,								
<b>AND</b>								
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,								
<b>AND</b>								
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.								
<b><u>Note</u></b>								
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).								
<b><u>Note</u></b>								
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).								
<b><u>Note</u></b>								
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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>								
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

## 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 vial)
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### ***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

#### **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.

## 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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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](http://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
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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**

## 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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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.

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](http://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.

## 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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**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:

- (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

## 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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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).

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

## 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
	bortezomib.						
	<b>Note</b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	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						
	<b>Note</b>						
	Special Pricing Arrangements apply.						
4706Q	Injection	3000 mcg	15	..	*1816.12	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.

## 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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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](http://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
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### **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

## 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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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**

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:

## 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
	<p>(a) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(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</p> <p>(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.</p> <p>Diagnostic reports must be no more than one month old at the time of application.</p> <p>Where a response assessment is not submitted prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib.</p> <p>Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.</p> <p><b>Note</b> 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.</p> <p><b>Note</b> 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).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001</p> <p><b>Note</b> Special Pricing Arrangements apply.</p>						
4713C	Injection	3000 mcg	15	..	*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 - 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

## 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
	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.						
	<b>Note</b>						
	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 <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>						
	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						
	<b>Note</b>						
	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,

#### **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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

## 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	
	Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
	<b>Note</b> Special Pricing Arrangements apply.							
4732C	Injection	3000 mcg	15	..	*1571.25	37.70	Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)	JC
	<b>ERIBULIN</b> <b>Authority required (STREAMLINED)</b> <b>4649</b> Locally advanced or metastatic breast cancer							
	<b>Clinical criteria:</b> Patient must have progressive disease, <b>AND</b> Patient must have failed at least two prior chemotherapeutic regimens for this condition, <b>AND</b> The treatment must be the sole PBS-subsidised therapy for this condition.							
	<b>Note</b> A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.							
	<b>Note</b> 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
	<b>IRINOTECAN</b> <b>Note</b> 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	..	*210.58	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
							Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)	UA
							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 40 mg/2 mL injection, 1 x 2 mL vial)	SZ

## 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	
							trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)	
							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 100 mg/5 mL injection, 1 x 5 mL vial)	GN
							Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)	GN
							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	..	*217.07	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	<sup>a</sup> Granisetron Kabi	PK
							<sup>a</sup> Granisetron-AFT	AE
							<sup>a</sup> 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	..	..	8.23	9.38	<sup>a</sup> APO-Ondansetron	TX
							<sup>a</sup> Ondansetron AN	EA
							<sup>a</sup> Ondansetron-DRLA	RZ
							<sup>a</sup> Ondaz	SZ
							<sup>a</sup> Onsetron 4	ZP
							<sup>a</sup> Zofran	AS
5968D	ondansetron 8 mg tablet, 4	1	..	..	12.89	14.04	<sup>a</sup> APO-Ondansetron	TX
							<sup>a</sup> Ondansetron AN	EA
							<sup>a</sup> Ondansetron-DRLA	RZ
							<sup>a</sup> Ondaz	SZ
							<sup>a</sup> Onsetron 8	ZP
							<sup>a</sup> Zofran	AS
5971G	ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	1	..	..	.90	2.05	<sup>a</sup> Ondansetron Alphapharm	AF
							<sup>a</sup> Ondansetron Kabi	PK
							<sup>a</sup> Ondansetron-Clarix	AE
							<sup>a</sup> Ondaz	SZ
							<sup>a</sup> Onsetron	ZP
5972H	ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	1	..	..	1.43	2.58	<sup>a</sup> Ondansetron Alphapharm	AF
							<sup>a</sup> Ondansetron Kabi	PK
							<sup>a</sup> Ondansetron-Clarix	AE
							<sup>a</sup> Ondaz	SZ
							<sup>a</sup> 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						
	<b>Note</b> 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	..	..	8.23	9.38	<sup>a</sup> Ondansetron AN ODT EA
							<sup>a</sup> Ondansetron ODT-DRLA RZ
							<sup>a</sup> Onsetron ODT 4 GN
5969E	ondansetron 4 mg wafer, 4	1	..	..	8.23	9.38	<sup>a</sup> Ondaz Zydis SZ
							<sup>a</sup> 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	..	..	12.89	14.04	<sup>a</sup> Ondansetron AN ODT EA
							<sup>a</sup> Ondansetron ODT-DRLA RZ
							<sup>a</sup> Onsetron ODT 8 GN
5970F	ondansetron 8 mg wafer, 4	1	..	..	12.89	14.04	<sup>a</sup> Ondaz Zydis SZ
							<sup>a</sup> 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	..	..	9.77	10.92	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
	<b>AND</b>						
	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.						
	<b><u>Authority required (STREAMLINED)</u></b>						
	<b>4216</b>						
	Nausea and vomiting						
	<b>Clinical criteria:</b>						
	The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer,						
	<b>AND</b>						
	The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,						
	<b>AND</b>						
	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.						
	<b><u>Authority required (STREAMLINED)</u></b>						
	<b>4217</b>						
	Nausea and vomiting						
	<b>Clinical criteria:</b>						
	The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy,						
	<b>AND</b>						
	The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle,						
	<b>AND</b>						
	Patient must have had a prior episode of chemotherapy induced nausea or vomiting,						
	<b>AND</b>						
	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.						
	<b><u>Note</u></b>						
	Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.						
	<b><u>Note</u></b>						
	No increase in the maximum quantity or number of units may be authorised.						
	<b><u>Note</u></b>						
	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.								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>3180</b>								
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
<b>INTERFERON ALFA-2B</b>								
<b><u>Caution</u></b>								
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.								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>3898</b>								
Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>3895</b>								
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
<b><i>Other immunostimulants</i></b>								
<b>BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN</b>								
<b><u>Restricted benefit</u></b>								
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
<b>BACILLUS CALMETTE AND GUERIN-TICE STRAIN</b>								
<b><u>Restricted benefit</u></b>								
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 \$	Brand Name and Manufacturer	
5904R	folinic acid 15 mg tablet, 10	1	..	..	76.00	37.70	Leucovorin Calcium (Hospira Pty Limited)	HH
<b>MESNA</b>								
<b><u>Restricted benefit</u></b>								
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
5961R	mesna 1 g/10 mL injection, 15 x 10 mL ampoules	1	5	..	185.44	37.70	Uromitexan	BX

## **GENERIC/PROPRIETARY INDEX**

**A**

<i>Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial) (TS)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Adcetris (brentuximab vedotin 50mg injection, 1 x 50 mg vial) (TK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	24, 62
<i>Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial) (LY)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
<i>Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial) (LY)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
<i>Aloxi (TS)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Anzatax (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Anzatax (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Anzatax (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Anzatax (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>APO-Ondansetron (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
APREPITANT	
.ALIMENTARY TRACT AND METABOLISM .....	89
ARSENIC	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	36, 74
<i>Avastin (bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial) (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	22, 23, 60, 61
<i>Avastin (bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial) (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	22, 23, 60, 61

**B**

BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	92
BACILLUS CALMETTE AND GUERIN-TICE STRAIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	92
BEVACIZUMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 22, 59, 60
<i>Bleo 15K (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	12, 50
BLEOMYCIN SULFATE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	12, 50
BORTEZOMIB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	36, 37, 39, 40, 43, 44, 45, 74, 75, 77, 79, 80, 82, 83
BRENTUXIMAB VEDOTIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	23, 24, 61, 62

**C**

CABAZITAXEL	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial) (JC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Caelyx (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial) (JC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Calcium Folate Ebewe (SZ)</i>	
.VARIOUS .....	93
<i>Carbaccord (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Carbaccord (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial) (GN)</i>	

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
CARBOPLATIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Carboplatin Kabi (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
CETUXIMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	24, 25, 26, 62, 63, 64
CISPLATIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Cisplatin Ebewe (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
CLADRIBINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
CYCLOPHOSPHAMIDE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
CYTARABINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53

## D

<i>DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>DBL Gemcitabine for Injection (gemcitabine 1 g injection, 1 x 1 g vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>DBL Gemcitabine for Injection (gemcitabine 2 g injection, 1 x 2 g vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>DBL Gemcitabine for Injection (gemcitabine 200 mg injection, 1 x 200 mg vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>DBL Gemcitabine Injection (gemcitabine 1 g/26.3 mL injection, 1 x 26.3 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>DBL Gemcitabine Injection (gemcitabine 2 g/52.6 mL injection, 1 x 52.6 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>DBL Gemcitabine Injection (gemcitabine 200 mg/5.3 mL injection, 1 x 5.3 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>DBL Oxaliplatin Concentrate (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>DBL Oxaliplatin Concentrate (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
DOCETAXEL	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
DOXORUBICIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57

<i>Doxorubicin MYX (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (YN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Doxorubicin SZ (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (HX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Doxorubicin SZ (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (HX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57

## E

<i>Eloxatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Eloxatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Eloxatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Emend (MK)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	90
<i>Endoxan (cyclophosphamide 1 g injection, 1 x 1 g vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Endoxan (cyclophosphamide 2 g injection, 1 x 2 g vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Endoxan (cyclophosphamide 500 mg injection, 1 x 500 mg vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<b>EPIRUBICIN</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Epirubicin ACT (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) (VN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin ACT (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (VN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin ACT (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (VN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Actavis 20 (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Ebewe (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Ebewe (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Ebewe (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Ebewe (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin Kabi (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Epirubicin SZ (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (HX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial) (SG)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	25, 26, 63, 64
<i>Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) (SG)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	25, 26, 63, 64
<b>ERIBULIN</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Etopophos (etoposide 1 g injection, 1 x 1 g vial) (BQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Etopophos (etoposide 100 mg injection, 1 x 100 mg vial) (BQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<b>ETOPOSIDE</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Etoposide Ebewe (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55

## F

<i>Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial) (GN)</i>	
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.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials) (GZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
FLUDARABINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
<i>Fludarabine ACT (fludarabine phosphate 50 mg injection, 1 x 50 mg vial) (VN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
FLUOROURACIL	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
FOLINIC ACID	
.VARIOUS .....	93
FOTEMUSTINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51

## G

<i>Gemaccord (gemcitabine 1 g injection, 1 x 1 g vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemaccord (gemcitabine 200 mg injection, 1 x 200 mg vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
GEMCITABINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Gemcitabine Actavis (gemcitabine 1 g injection, 1 x 1 g vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Actavis 2000 (gemcitabine 2 g injection, 1 x 2 g vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Ebewe (gemcitabine 1 g injection, 1 x 1 g vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Ebewe (gemcitabine 1 g/100 mL injection, 1 x 100 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Ebewe (gemcitabine 200 mg injection, 1 x 200 mg vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Ebewe (gemcitabine 200 mg/20 mL injection, 1 x 20 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Ebewe (gemcitabine 500 mg/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Kabi (gemcitabine 1 g injection, 1 x 1 g vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Sun (gemcitabine 1 g injection, 1 x 1 g vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Gemcitabine Sun (gemcitabine 200 mg injection, 1 x 200 mg vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
GRANISETRON	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Granisetron Kabi (PK)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Granisetron-AFT (AE)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88

## H

<i>Halaven (eribulin mesilate 1 mg/2 mL injection, 1 x 2 mL vial) (EI)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84

<i>Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	32, 33, 35, 70, 71, 73
<i>Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	32, 33, 35, 70, 71, 73
<i>Holoxan (ifosfamide 1 g injection, 1 x 1 g vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Holoxan (ifosfamide 2 g injection, 1 x 2 g vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Hospira Pty Limited (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	12, 50
<i>Hospira Pty Limited (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Hospira Pty Limited (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Hospira Pty Limited (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Hospira Pty Limited (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Hospira Pty Limited (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Hospira Pty Limited (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Hospira Pty Limited (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Hospira Pty Limited (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Hospira Pty Limited (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Hospira Pty Limited (flourouracil 500 mg/10 mL injection, 5 x 10 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Hospira Pty Limited (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Hospira Pty Limited (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Hospira Pty Limited (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Hospira Pty Limited (oxaliplatin 100 mg injection, 1 x 100 mg vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Hospira Pty Limited (vinorelbine 10 mg/mL injection, 1 x 1 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Hospira Pty Limited (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials) (GK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85

## I

IDARUBICIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Idarubicin Ebewe (idarubicin hydrochloride 10 mg/10 mL injection, 1 x 10 mL vial) (SZ)</i>	

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Idarubicin Ebewe (idarubicin hydrochloride 5 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<b>IFOSFAMIDE</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>ImmuCyst (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	92
<b>INTERFERON ALFA-2A</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	91
<b>INTERFERON ALFA-2B</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	91, 92
<i>Intron A Redipen (MK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	92
<b>IPILIMUMAB</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	26, 27, 64, 65
<i>Irinocord (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinocord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<b>IRINOTECAN</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	46, 84
<i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Irinotecan Kabi (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Irinotecan MYX (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (YN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85

## J

<i>Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55

## K

<i>Kytril (RO)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88

## L

<i>Leucovorin Calcium (Hospira Pty Limited) (HH)</i>	
.VARIOUS .....	93, 94
<i>Leucovorin Calcium (Pfizer Australia Pty Ltd) (PF)</i>	
.VARIOUS .....	93
<i>Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial) (JC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
<i>Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Liposomal Doxorubicin SUN (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial) (ZF)</i>	

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	19, 57
<i>Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial) (OA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52

## M

<i>Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	29, 30, 31, 67, 68, 69
<i>Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial) (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	29, 30, 31, 67, 68, 69
MESNA	
.VARIOUS .....	94
<i>Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 14, 51, 52
<i>Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 14, 51, 52
METHOTREXATE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51
<i>Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 14, 51, 52
<i>Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 14, 51, 52
<i>Methotrexate MYX (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (YN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 14, 51, 52
<i>Methotrexate MYX (METHOTREXATE Injection 50 mg in 2 mL, 1) (YN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 14, 51, 52
MITOZANTRONE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Mitozantrone Ebewe (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&amp;) inert substance diluent [1 x 4 mL ampoule], 1 pack) (SE)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	13, 51

## N

<i>Navelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial) (FB)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Navelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (FB)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54

## O

<i>Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (OE)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (OE)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>OncoTICE (MK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	92
ONDANSETRON	
.ALIMENTARY TRACT AND METABOLISM .....	88, 89
<i>Ondansetron Alphapharm (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Ondansetron AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Ondansetron AN ODT (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Ondansetron Kabi (PK)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Ondansetron ODT-DRLA (RZ)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Ondansetron-Clarix (AE)</i>	

.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Ondansetron-DRLA (RZ)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Ondaz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Ondaz Zydys (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Onkotrone (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Onkotrone (mitozantrone 25 mg/12.5 mL injection, 1 x 12.5 mL vial) (BX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Onsetron (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Onsetron 4 (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Onsetron 8 (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	88
<i>Onsetron ODT 4 (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Onsetron ODT 8 (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Oxaliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<b>OXALIPLATIN</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin Ebewe (oxaliplatin 50 mg injection, 1 x 50 mg vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin MYX (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (YN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin SUN (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin SUN (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin SUN (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (ZF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59
<i>Oxaliplatin SZ (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (HX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	21, 59

## P

<b>PACLITAXEL</b>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Paclitaxel Actavis (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Ebewe (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56

<i>Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Kabi (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Paclitaxel Kabi (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
PACLITAXEL NANOPARTICLE ALBUMIN BOUND	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
PALONOSETRON	
.ALIMENTARY TRACT AND METABOLISM .....	89
PANITUMUMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	28, 66
PEMETREXED	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
<i>Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials) (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	15, 53
<i>Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) (PL)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	36, 74
<i>Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56
<i>Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	18, 56

## R

RALTITREXED	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
RITUXIMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	29, 30, 31, 67, 68, 69
<i>Roferon-A (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	91

## T

<i>Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55
<i>Tecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial) (HH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	14, 52
TOPOTECAN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Topotecan Agila (topotecan 4 mg injection, 1 x 4 mg vial) (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
<i>Topotecan Kabi (topotecan 4 mg injection, 5 x 4 mg vials) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	47, 85
TRASTUZUMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	31, 33, 35, 69, 71, 73
TROPISETRON	
.ALIMENTARY TRACT AND METABOLISM .....	89
<i>Tropisetron-AFT (AE)</i>	
.ALIMENTARY TRACT AND METABOLISM .....	89

## U

<i>Uromitexan (BX)</i>	
.VARIOUS .....	94

## V

<i>Vectibix (panitumumab 100 mg/5 mL injection, 1 x 5 mL vial) (AN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	29, 67
<i>Vectibix (panitumumab 400 mg/20 mL injection, 1 x 20 mL vial) (AN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	29, 67
<i>Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) (JC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	37, 45, 46, 75, 77, 84
<i>Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) (JC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	39, 40, 43, 44, 79, 80, 82, 83
VINBLASTINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
VINCRISTINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
VINORELBINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Vinorelbine Ebewe (vinorelbine 10 mg/mL injection, 1 x 1 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	16, 54
<i>Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (PK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	17, 55

## Y

<i>Yervoy (ipilimumab 200 mg/40 mL injection, 1 x 40 mL vial) (BQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	27, 28, 65, 66
<i>Yervoy (ipilimumab 50 mg/10 mL injection, 1 x 10 mL vial) (BQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	27, 28, 65, 66

## Z

<i>Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6) (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
<i>Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3) (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....	20, 58
Zofran (AS)	
.ALIMENTARY TRACT AND METABOLISM .....	88
Zofran syrup 50 mL (AS)	
.ALIMENTARY TRACT AND METABOLISM .....	88
Zofran Zydys (AS)	
.ALIMENTARY TRACT AND METABOLISM .....	89