



**Australian Government**

**Department of Health and Ageing**

**SCHEDULE OF PHARMACEUTICAL  
BENEFITS FOR APPROVED PHARMACISTS  
AND MEDICAL PRACTITIONERS**

**CHEMOTHERAPY PHARMACEUTICALS  
ACCESS PROGRAM SUPPLEMENT**

This Schedule is also available on the internet at

[www.pbs.gov.au](http://www.pbs.gov.au)

**EFFECTIVE 1 July 2011 -**

**31 July 2011**

**(ALL PREVIOUS EDITIONS CANCELLED)**



# SUMMARY OF CHANGES

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

### Additions

#### Additions – Items

5809R	<b>Docetaxel</b> , Solution concentrate for I.V. infusion 140 mg in 7 mL ( <i>Oncotaxel 140</i> )
5810T	<b>Docetaxel</b> , Solution concentrate for I.V. infusion 140 mg in 7 mL ( <i>Oncotaxel 140</i> )
5807P	<b>Fluorouracil</b> , Injection 2500 mg in 50 mL ( <i>Fluorouracil Ebewe</i> )
5808Q	<b>Fluorouracil</b> , Injection 5000 mg in 100 mL ( <i>Fluorouracil Ebewe</i> )

#### Additions – Brands

5854D	<i>Oncotaxel 20, TA</i> – <b>Docetaxel</b> , Solution concentrate for I.V. infusion 20 mg in 1 mL
5855E	<i>Oncotaxel 20, TA</i> – <b>Docetaxel</b> , Solution concentrate for I.V. infusion 20 mg in 1 mL
5864P	<i>Oncotaxel 20, TA</i> – <b>Docetaxel</b> , Solution concentrate for I.V. infusion 20 mg in 1 mL
5856F	<i>Oncotaxel 80, TA</i> – <b>Docetaxel</b> , Solution concentrate for I.V. infusion 80 mg in 4 mL
5867T	<i>Oncotaxel 80, TA</i> – <b>Docetaxel</b> , Solution concentrate for I.V. infusion 80 mg in 4 mL
5992J	<i>Vinorelbine Kabi, PK</i> – <b>Vinorelbine</b> , Solution for I.V. infusion 10 mg (as tartrate) in 1 mL
5993K	<i>Vinorelbine Kabi, PK</i> – <b>Vinorelbine</b> , Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

### Deletions

#### Deletions – Brands

5903Q	<i>Blenamax, QA</i> – <b>Bleomycin Sulfate</b> , Powder for injection 15,000 i.u. (code 6896Y applies to above item with approved solvent)
5958N	<i>Irinotecan Sandoz, SZ</i> – <b>Irinotecan Hydrochloride Trihydrate</b> , I.V. injection 40 mg in 2 mL
5959P	<i>Irinotecan Sandoz, SZ</i> – <b>Irinotecan Hydrochloride Trihydrate</b> , I.V. injection 100 mg in 5 mL

#### Deletion – Bioequivalence Indicator

5903Q	<i>Hospira Pty Limited, HH</i> – <b>Bleomycin Sulfate</b> , Powder for injection 15,000 i.u. (code 6896Y applies to above item with approved solvent)
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### Alterations

#### Alterations – Item Descriptions

From:

5992J **Vinorelbine Tartrate**, Solution for I.V. infusion 10 mg (base) in 1 mL (*Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link*)

To:

5992J **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL (*Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link, Vinorelbine Kabi*)

From:

5993K **Vinorelbine Tartrate**, Solution for I.V. infusion 50 mg (base) in 5 mL (*Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link*)

To:

5993K **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL (*Hospira Pty Limited, Navelbine, Vinorelbine Ebewe, Vinorelbine Link, Vinorelbine Kabi*)

### Alterations – Number of Repeats

		<i>From:</i>	<i>To:</i>
5888X	<b>Aprepitant</b> , Pack containing 1 capsule 125 mg and 2 capsules 80 mg ( <i>Emend</i> )	0	5

### Alteration – Note

5888X **Aprepitant**, Pack containing 1 capsule 125 mg and 2 capsules 80 mg (*Emend*)

### Alterations – Manufacturer's Codes

All items with the manufacturer code SH have changed to the code MK.

All items with the manufacturer code IT have changed to the code SZ, with the exception of the brand Docetaxel Ebewe in all available forms which will change from IT to the code HX.

		<i>From:</i>	<i>To:</i>
5992J	<i>Vinorelbine Link, FU</i> – <b>Vinorelbine</b> , Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	PK	FU
5993K	<i>Vinorelbine Link, FU</i> – <b>Vinorelbine</b> , Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	PK	FU

### Advance Notices

#### Advance Notices – Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2011:

Brands discontinued by the manufacturer—

5992J *Vinorelbine Link, FU* – **Vinorelbine**, Solution for I.V. infusion 10 mg (as tartrate) in 1 mL

5993K *Vinorelbine Link, FU* – **Vinorelbine**, Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

## 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 chemotherapy drugs for day only admitted and non-admitted patients of Public Hospitals

The adoption of the Australian Government's pharmaceutical reforms will see a change to the access arrangements for cancer chemotherapy drugs for public hospitals.

A range of currently listed PBS cancer chemotherapy agents have been transferred to section 100 funding arrangements to facilitate access to day admitted and non-admitted patients. Benefits are available for the listed chemotherapy drugs only. There is no facility for individual approval for chemotherapy drugs outside those listed.

To gain access to a Commonwealth funded drug under this arrangement a patient must attend a participating public hospital and be a day admitted or non-admitted patient. Only a medical practitioner, in the course of employment with the participating public hospital, may prescribe the subsidised medication.

Chemotherapy drugs claimed under this arrangement may only be supplied by an approved hospital authority and only dispensed by the hospital pharmacy.

All drugs supplied under these arrangements will have a patient copayment deducted from the Commonwealth reimbursement price. Under the provisions of the National Healthcare Agreement, copayments cannot be raised, by the hospital, for drugs supplied to day admitted patients. Copayments can be raised and collected, by the hospital, for non-admitted patients.

If you would like further information about the special arrangements for section 100 chemotherapy drugs, please contact the State Government adviser:

Victoria	(03) 9096 2506
Queensland	(07) 3636 9830
Western Australia	(08) 9388 4980
Northern Territory	(08) 8999 2448

As of 1 September 2009, some of the chemotherapy pharmaceuticals that are available for supply under the Program no longer require an authority from the Medicare Australia CEO. Medical practitioners who prescribe these drugs to their patients (and approved hospital authorities acting on their behalf) only need to record a four digit streamlined authority code on the patient's medication chart to indicate that these drugs have been prescribed in accordance with the restrictions set out in this schedule.

For more information on how to prescribe these 'Authority required (STREAMLINED)' items, refer to the Explanatory Notes of the Schedule of Pharmaceutical Benefits at [www.pbs.gov.au](http://www.pbs.gov.au) or the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au).

For further information on streamlined authority arrangements, visit the Department of Health and Ageing website at [www.health.gov.au/pbsreform](http://www.health.gov.au/pbsreform).

## Index of Manufacturers' Codes

<i>Code</i>	<i>Manufacturer</i>	<i>Code</i>	<i>Manufacturer</i>
AE	AFT Pharmaceuticals Pty Ltd Level 1, 296 Burns Bay Road Lane Cove NSW 2066 Tel: 1800 097 639 Fax: 1800 097 810	HH	Hospira Pty Ltd (David Bull Laboratories, Faulding Pharmaceuticals) Level 6, 390 St Kilda Road Melbourne Vic 3004 Tel: (03) 9868 0700 Fax: (03) 9868 0111
AF	Alphapharm Pty Limited Chase Building 2 Wentworth Park Road Glebe NSW 2037 Tel: (02) 9298 3999 Fax: (02) 9566 4686		
BQ	Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd 556 Princes Highway Noble Park Vic 3174 Tel: (03) 9213 4000 Fax: (03) 9701 1518	JC	Janssen-Cilag Pty Ltd 1-5 Khartoum Road North Ryde NSW 2113 Tel: (02) 8875 3333 Fax: (02) 8875 3300
BX	Baxter Healthcare Pty Limited 1 Baxter Drive Old Toongabbie NSW 2146 Tel: (02) 9848 1111 Fax: (02) 9848 1123	LY	Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410
FB	Pierre Fabre Medicament Australia Pty Limited Unit 26B, Parkview Business Centre 1 Maitland Place Baulkham Hills NSW 2153 Tel: (02) 8858 2800 Fax: (02) 8858 2888	MK	Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595
GK	GlaxoSmithKline Australia Pty Ltd Level 4, 436-438 Johnston Street Abbotsford Vic 3067 Tel: (03) 9413 7300 Fax: (03) 8761 2410	NV	Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551
GQ	Generic Health Pty Ltd Suite 1, Level 1 1175 Toorak Road Camberwell Vic 3124 Tel: (03) 9809 7900 Fax: (03) 9809 7999	OA	Orphan Australia Pty Ltd 300 Frankston-Dandenong Road Dandenong Vic 3175 Tel: (03) 9709 2200 Fax: (03) 9709 2299
GZ	Genzyme Australasia Pty Ltd Level 1, Building C 12-24 Talavera Road North Ryde NSW 2113 Tel: (02) 9978 3900 Fax: (02) 9889 3900	OE	Omegapharm Pty Ltd 21 Queen Street Ormond Vic 3204 Tel: (03) 9483 0070 Fax: (03) 9483 0070
		PF	Pfizer Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347

## Index of Manufacturers' Codes

<i>Code</i>	<i>Manufacturer</i>	<i>Code</i>	<i>Manufacturer</i>
PK	Fresenius Kabi Australia Pty Limited 964 Pacific Highway Pymble NSW 2073 Tel: 1300 732 001 Fax: 1300 304 384	TS	Specialised Therapeutics Australia Pty Ltd Level 1, 711 High Street Kew East Vic 3102 Tel: 1300 798 820 Fax: 1800 798 829
PL	Phebra 332 Burns Bay Road Lane Cove NSW 2066 Tel: (02) 9420 9199 Fax: (02) 9420 9177	TX	Apotex Pty Ltd 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377
QA	Aspen Pharma Pty Ltd 96 Merrindale Drive Croydon Vic 3136 Tel: (03) 9839 2800 Fax: (03) 9839 2802	WA	Winthrop Pharmaceuticals Division of Sanofi-Aventis Australia Pty Limited Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000
RO	Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9971 7401	WQ	Willow Pharmaceuticals Pty Limited Level 31, ABN Amro Tower 88 Phillip Street Sydney NSW 2000 Tel: (02) 9518 1735 Fax: (02) 9518 1835
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd Level 1, 181 Bay Street Brighton Vic 3186 Tel: (03) 9595 3812 Fax: (03) 9595 3800	ZF	Sun Pharmaceutical Industries (Australia) Pty Ltd 1053 Burwood Highway Ferntree Gully Vic 3156 Tel: (03) 9568 6102 Fax: (03) 9568 6610
SE	Servier Laboratories (Aust.) Pty Ltd 8 Cato Street Hawthorn Vic 3122 Tel: (03) 8823 7333 Fax: (03) 9822 9790	ZP	Spirit Pharmaceuticals Pty Ltd 117 Harrington Street The Rocks Sydney NSW 2000 Tel: (02) 9251 1088 Fax: (02) 9251 1099
SG	Merck Serono Australia Pty Ltd Unit 3-4, 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: (02) 8977 4100 Fax: (02) 9975 1516		
SH	Schering-Plough Pty Ltd Level 4, 66 Waterloo Road North Ryde NSW 2113 Tel: (02) 8988 8000 Fax: (02) 9852 7500		
SW	Sanofi-Aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: (02) 8666 2000 Fax: (02) 8666 3000		
SZ	Sandoz Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458		

## SPECIAL PHARMACEUTICAL BENEFITS

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 and Form	Max. Qty	No. of Rpts	Premium	Reimbursement Price for Max. Qty \$	Dispensed Price for Max. Qty \$	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;

Lymphoma.

5903Q	Powder for injection 15,000 i.u.	10	..	\$367.80	*408.90	*776.70	34.20	Hospira Pty Limited	HH
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## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	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 (5HT<sub>3</sub>) antagonists*

##### **DOLASETRON MESYLATE**

##### **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.

5923R	Tablet 200 mg	2	..	..	37.02	34.20	Anzemet	SW
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##### **GRANISETRON HYDROCHLORIDE**

##### **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.

5898K	Tablet 2 mg (base)	2	..	..	*44.44	34.20	Kytril	HH
5899L	Concentrated injection 3 mg (base) in 3 mL	1	..	..	25.42	26.49	a Kytril	HH
					*25.57	26.64	a Granisetron Kabi	PK

##### **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**

Bioequivalence has been demonstrated between the orally disintegrating tablets and wafers.

5857G	Tablet (orally disintegrating) 4 mg	4	..	..	26.17	27.24	a Ondansetron ODT-DRLA	RZ
5858H	Tablet (orally disintegrating) 8 mg	4	..	..	40.99	34.20	a Ondansetron ODT-DRLA	RZ
5969E	Wafer 4 mg	4	..	..	26.17	27.24	a Ondaz Zydis	SZ
							a Zofran Zydis	GK
5970F	Wafer 8 mg	4	..	..	40.99	34.20	a Ondaz Zydis	SZ
							a Zofran Zydis	GK

##### **ONDANSETRON**

##### **Restricted benefit**

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

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

5848T	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	#1	..	..	66.76	34.20	Zofran syrup 50 mL	GK
5967C	Tablet 4 mg (as hydrochloride dihydrate)	4	..	..	26.17	27.24	a APO-Ondansetron	TX
							a Ondansetron-DRLA	RZ
							a Ondaz	SZ
							a Onsetron 4	ZP
							a Zofran	GK
5968D	Tablet 8 mg (as hydrochloride dihydrate)	4	..	..	40.99	34.20	a APO-Ondansetron	TX
							a Ondansetron-DRLA	RZ

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer		
					for Max. Qty \$	Recordable Value for Safety Net \$			
5971G	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	1	..	..	10.93	12.00	a	Ondaz	SZ
								Onsetron 8	ZP
								Zofran	GK
								Ondansetron-Claris	AE
								Ondaz	SZ
5972H	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	1	..	..	17.37	18.44	a	Onsetron	ZP
								Pfizer Australia Pty Ltd	PF
								Zofran	GK
								Ondansetron-Claris	AE
								Ondaz	SZ
							a	Onsetron	ZP
								Pfizer Australia Pty Ltd	PF
								Zofran	GK
								Ondansetron-Claris	AE
								Ondaz	SZ

### 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	Injection 250 micrograms (as hydrochloride) in 5 mL	1	..	..	34.36	34.20	Aloxi	TS
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### TROPISETRON HYDROCHLORIDE

#### **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.

5986C	Capsule 5 mg (base)	2	..	..	37.02	34.20	Navoban	NV
5987D	I.V. injection 5 mg (base) in 5 mL	1	..	..	18.50	19.57	Navoban	NV

### **Other antiemetics**

#### APREPITANT

#### **Note**

Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

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

##### **3619**

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

- (a) altretamine;
- (b) carmustine;
- (c) cisplatin when a single dose constitutes a cycle of chemotherapy;
- (d) cyclophosphamide at a dose of 1500 mg per square metre per day or greater;
- (e) dacarbazine;
- (f) procarbazine when a single dose constitutes a cycle of chemotherapy;
- (g) streptozocin.

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

##### **3620**

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer, in combination with a 5HT3 antagonist and dexamethasone, where cyclophosphamide and an anthracycline are to be co-administered.

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

##### **3621**

Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	vomiting where any 1 of the following intravenous chemotherapy agents is to be administered:						
	(a) arsenic trioxide;						
	(b) azacitidine;						
	(c) carboplatin;						
	(d) cyclophosphamide at a dose of less than 1500 mg per square metre per day;						
	(e) cytarabine at a dose of greater than 1 g per square metre per day;						
	(f) dactinomycin;						
	(g) daunorubicin;						
	(h) doxorubicin;						
	(i) epirubicin;						
	(j) fotemustine;						
	(k) idarubicin;						
	(l) ifosfamide;						
	(m) irinotecan;						
	(n) melphalan;						
	(o) methotrexate at a dose of 250 mg to 1 g per square metre;						
	(p) oxaliplatin;						
	(q) raltitrexed.						
	No more than one pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.						
	<b>Note</b>						
	No applications for increased maximum quantities and/or repeats will be authorised.						
5888X	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	#1	5	..	112.01	34.20	Emend MK

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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# Antineoplastic and immunomodulating agents

### Antineoplastic agents

#### Alkylating agents

##### *Nitrogen mustard analogues*

###### CYCLOPHOSPHAMIDE

5914G	Powder for injection 500 mg	2	..	..	*27.72	28.79	Endoxan	BX
5915H	Powder for injection 1 g	1	..	..	21.21	22.28	Endoxan	BX
5916J	Powder for injection 2 g	1	..	..	42.43	34.20	Endoxan	BX

###### IFOSFAMIDE

###### Restricted benefit

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

Relapsed or refractory sarcomas following first-line chemotherapy.

5943T	Powder for I.V. injection 1 g	5	5	..	*295.75	34.20	Holoxan	BX
5944W	Powder for I.V. injection 2 g	5	5	..	*592.00	34.20	Holoxan	BX

##### *Ethylene imines*

###### THIOTEPA

5984Y	Powder for injection 15 mg	2	1	..	*126.20	34.20	Aspen Pharma Pty Ltd	QA
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##### *Nitrosoureas*

###### FOTEMUSTINE

###### Authority required (STREAMLINED)

3181

Metastatic malignant melanoma.

5900M	Powder for injection 208 mg with solvent	1	4	..	1084.33	34.20	Muphoran	SE
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#### Antimetabolites

##### *Folic acid analogues*

###### METHOTREXATE

5873D	Solution concentrate for I.V. infusion 500 mg in 20 mL	1	..	..	47.11	34.20	Hospira Pty Limited	HH
5875F	Solution concentrate for I.V. infusion 1000 mg in 10 mL	1	..	..	94.21	34.20	<sup>a</sup> Hospira Pty Limited	HH
							<sup>a</sup> Methotrexate Ebewe	SZ
5876G	Solution concentrate for I.V. infusion 5000 mg in 50 mL	1	..	..	471.05	34.20	Methotrexate Ebewe	SZ
5962T	Injection 5 mg in 2 mL	5	..	..	24.09	25.16	Hospira Pty Limited	HH
5963W	Injection 50 mg in 2 mL	5	..	..	23.54	24.61	<sup>a</sup> Hospira Pty Limited <sup>a</sup> Pfizer Australia Pty Ltd	HH PF

###### PEMETREXED DISODIUM

###### Authority required

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

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

###### Authority required

Mesothelioma in combination with cisplatin.

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

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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

**Note**

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

5834C	Powder for I.V. infusion 500 mg (base)	1	3	..	1559.86	34.20	Alimta	LY
5835D	Powder for I.V. infusion 100 mg (base)	1	3	..	311.97	34.20	Alimta	LY

**RALTITREXED****Authority required (STREAMLINED)****3185**

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

5977N	Powder for I.V. infusion 2 mg	3	2	..	*760.02	34.20	Tomudex	HH
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**Purine analogues****CLADRIBINE****Authority required (STREAMLINED)****3180**

Hairy cell leukaemia.

5889Y	Injection 10 mg in 5 mL	7	..	..	*4483.22	34.20	Litak	OA
5912E	Solution for I.V. infusion 10 mg in 10 mL	7	..	..	*4483.22	34.20	Leustatin	JC

**FLUDARABINE PHOSPHATE****Authority required**

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

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

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

- (a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and  
 (b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.

**Note**

The solution for I.V. injection and powder for I.V. injection (after reconstitution) are bioequivalent.

5840J	Powder for I.V. injection 50 mg	5	3	..	1371.22	34.20	<sup>a</sup> Fludara	GZ
				..	*1371.25	34.20	<sup>a</sup> Farine	WQ
							<sup>a</sup> Fludarabine Actavis	GQ
5841K	Solution for I.V. injection 50 mg in 2 mL	5	3	..	1371.22	34.20	<sup>a</sup> Fludarabine Ebewe	SZ

**Pyrimidine analogues****CYTARABINE**

5918L	Injection 100 mg in 5 mL	10	1	..	*100.92	34.20	Pfizer Australia Pty Ltd	PF
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**FLUOROURACIL**

5807P	Injection 2500 mg in 50 mL	2	..	..	*34.70	34.20	Fluorouracil Ebewe	SZ
5808Q	Injection 5000 mg in 100 mL	1	..	..	34.69	34.20	Fluorouracil Ebewe	SZ
5872C	Injection 1000 mg in 20 mL	5	..	..	*34.70	34.20	Fluorouracil Ebewe	SZ
5935J	Injection 500 mg in 10 mL	10	..	..	*40.82	34.20	<sup>a</sup> Fluorouracil Ebewe	SZ
							<sup>a</sup> Hospira Pty Limited	HH

**GEMCITABINE****Authority required**

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

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

Locally advanced or metastatic non-small cell lung cancer;

Locally advanced or metastatic adenocarcinoma of the pancreas;

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum		Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$		
Locally advanced or metastatic bladder cancer, in combination with cisplatin.								
<b>Note</b>								
The powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution) and the solution concentrate for I.V. infusion 200 mg (as hydrochloride) are bioequivalent.								
5843M	Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL	4	2	..	*106.28	34.20	<sup>a</sup>	Gemcitabine Ebewe SZ
5936K	Powder for I.V. infusion 200 mg (as hydrochloride)	4	2	..	*106.28	34.20	<sup>a</sup>	DBL Gemcitabine for Injection HH
							<sup>a</sup>	Gemcitabine Actavis GQ
							<sup>a</sup>	Gemcitabine Ebewe SZ
							<sup>a</sup>	Gemcitabine Kabi PK
							<sup>a</sup>	Gemcitabine Sun ZF
							<sup>a</sup>	Gemcite ZP
							<sup>a</sup>	Gemplan WQ
							<sup>a</sup>	Gemzar LY

### GEMCITABINE

#### Authority required

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

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

Locally advanced or metastatic non-small cell lung cancer;

Locally advanced or metastatic adenocarcinoma of the pancreas;

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

#### Note

The powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution) and the solution concentrate for I.V. infusion 1000 mg (as hydrochloride) are bioequivalent.

5844N	Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL	2	2	..	*262.40	34.20	<sup>a</sup>	Gemcitabine Ebewe SZ
5937L	Powder for I.V. infusion 1 g (as hydrochloride)	2	2	..	*262.40	34.20	<sup>a</sup>	DBL Gemcitabine for Injection HH
							<sup>a</sup>	Gemcitabine Actavis GQ
							<sup>a</sup>	Gemcitabine Ebewe SZ
							<sup>a</sup>	Gemcitabine Kabi PK
							<sup>a</sup>	Gemcitabine Sun ZF
							<sup>a</sup>	Gemcite ZP
							<sup>a</sup>	Gemplan WQ
							<sup>a</sup>	Gemzar LY

### GEMCITABINE

#### Authority required

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

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

Locally advanced or metastatic non-small cell lung cancer;

Locally advanced or metastatic adenocarcinoma of the pancreas;

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

5845P	Powder for I.V. infusion 2 g (as hydrochloride)	1	2	..	262.99	34.20	<sup>a</sup>	DBL Gemcitabine for Injection HH
							<sup>a</sup>	Gemcitabine Kabi PK
5852B	Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL	4	2	..	*262.40	34.20		Gemcitabine Ebewe SZ

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<b>Plant alkaloids and other natural products</b>							
<b><i>Vinca alkaloids and analogues</i></b>							
<b>VINBLASTINE SULFATE</b>							
5989F	Solution for I.V. injection 10 mg in 10 mL	5	..	..	138.12	34.20	Hospira Pty Limited HH
<b>VINCRIStINE SULFATE</b>							
5991H	I.V. injection 1 mg in 1 mL	10	..	..	*123.28	34.20	<sup>a</sup> Hospira Pty Limited HH <sup>a</sup> Pfizer Australia Pty PF Ltd
<b>VINORELBINE</b>							
<b><u>Authority required</u></b>							
Advanced breast cancer after failure of prior therapy which includes an anthracycline; Locally advanced or metastatic non-small cell lung cancer.							
5992J	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL	16	2	..	*995.52	34.20	<sup>a</sup> Hospira Pty Limited HH <sup>a</sup> Navelbine FB <sup>a</sup> Vinorelbine Ebewe SZ <sup>a</sup> Vinorelbine Kabi PK <sup>a</sup> Vinorelbine Link FU
5993K	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL	4	2	..	*1041.60	34.20	<sup>a</sup> Hospira Pty Limited HH <sup>a</sup> Navelbine FB <sup>a</sup> Vinorelbine Ebewe SZ <sup>a</sup> Vinorelbine Kabi PK <sup>a</sup> Vinorelbine Link FU
<b><i>Podophyllotoxin derivatives</i></b>							
<b>ETOPOSIDE</b>							
5931E	Solution for I.V. infusion 100 mg in 5 mL	5	..	..	132.80 *132.80	34.20 34.20	<sup>a</sup> Etoposide Ebewe SZ <sup>a</sup> Hospira Pty Limited HH
5932F	Powder for I.V. infusion 100 mg (as phosphate)	5	..	..	*132.80	34.20	Etopophos BQ
5933G	Powder for I.V. infusion 1 g (as phosphate)	1	..	..	265.54	34.20	Etopophos BQ
<b><i>Taxanes</i></b>							
<b>DOCETAXEL</b>							
<b><u>Authority required</u></b>							
Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.							
<b><u>Note</u></b>							
The carcinoma can be considered inoperable for technical or organ preservation reasons.							
<b><u>Note</u></b>							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5842L	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	1	..	..	288.29	34.20	<sup>a</sup> Taxotere SW
5854D	Solution concentrate for I.V. infusion 20 mg in 1 mL	1	..	..	288.29	34.20	<sup>a</sup> Oncotaxel 20 TA <sup>a</sup> Taxotere SW
5859J	Solution concentrate for I.V. infusion 20 mg in 2 mL	1	..	..	288.29	34.20	<sup>a</sup> DBL Docetaxel Concentrated Injection HH <sup>a</sup> Docetaxel Ebewe HX

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price	Maximum	Brand Name and Manufacturer
					for Max. Qty \$	Recordable Value for Safety Net \$	
<b>DOCETAXEL</b>							
<b><u>Authority required</u></b> Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.							
<b><u>Note</u></b> The carcinoma can be considered inoperable for technical or organ preservation reasons.							
<b><u>Authority required</u></b> Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide; Advanced breast cancer after failure of prior therapy; Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound; Locally advanced or metastatic non-small cell lung cancer.							
<b><u>Authority required</u></b> Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.							
<b><u>Note</u></b> A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.							
<b><u>Note</u></b> The 80 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5856F	Solution concentrate for I.V. infusion 80 mg in 4 mL	1	..	..	1155.45	34.20 <sup>a</sup>	Oncotaxel 80 TA
						<sup>a</sup>	Taxotere SW
5861L	Solution concentrate for I.V. infusion 80 mg in 8 mL	1	..	..	1155.45	34.20 <sup>a</sup>	DBL Docetaxel Concentrated Injection HH
						<sup>a</sup>	Docetaxel Ebewe HX
5922Q	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	1	..	..	1155.45	34.20 <sup>a</sup>	Taxotere SW

### DOCETAXEL

#### **Authority required**

Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.

#### **Note**

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

#### **Authority required**

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

Advanced breast cancer after failure of prior therapy;

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

Locally advanced or metastatic non-small cell lung cancer.

#### **Authority required**

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

#### **Note**

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

5809R	Solution concentrate for I.V. infusion 140 mg in 7 mL	1	..	..	2013.30	34.20	Oncotaxel 140 TA
5862M	Solution concentrate for I.V. infusion 160 mg in 16 mL	1	..	..	2310.90	34.20	DBL Docetaxel Concentrated Injection HH

### DOCETAXEL

#### **Authority required**

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

#### **Authority required**

Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<b>Note</b>							
A maximum of four cycles of treatment will be authorised under this restriction.							
<b>Note</b>							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5864P	Solution concentrate for I.V. infusion 20 mg in 1 mL	2	..	..	*576.58	34.20 <sup>a</sup>	Oncotaxel 20 Taxotere SW
5865Q	Solution concentrate for I.V. infusion 20 mg in 2 mL	2	..	..	*576.58	34.20 <sup>a</sup>	DBL Docetaxel Concentrated Injection HH
5866R	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	2	..	..	*576.58	34.20 <sup>a</sup>	Taxotere SW
<hr/>							
<b>DOCETAXEL</b>							
<b>Authority required</b>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<b>Authority required</b>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							
<b>Note</b>							
A maximum of four cycles of treatment will be authorised under this restriction.							
<b>Note</b>							
The 80 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5867T	Solution concentrate for I.V. infusion 80 mg in 4 mL	1	..	..	1155.45	34.20 <sup>a</sup>	Oncotaxel 80 Taxotere SW
5868W	Solution concentrate for I.V. infusion 80 mg in 8 mL	1	..	..	1155.45	34.20 <sup>a</sup>	DBL Docetaxel Concentrated Injection HH
5869X	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	1	..	..	1155.45	34.20 <sup>a</sup>	Taxotere SW
<hr/>							
<b>DOCETAXEL</b>							
<b>Authority required</b>							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
<b>Authority required</b>							
Adjuvant treatment of operable breast cancer in combination with cyclophosphamide.							
<b>Note</b>							
A maximum of four cycles of treatment will be authorised under this restriction.							
5810T	Solution concentrate for I.V. infusion 140 mg in 7 mL	1	..	..	2013.30	34.20	Oncotaxel 140 TA
5957M	Solution concentrate for I.V. infusion 160 mg in 16 mL	1	..	..	2310.90	34.20	DBL Docetaxel Concentrated Injection HH
<hr/>							
<b>DOCETAXEL</b>							
<b>Authority required</b>							
Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide;							
Advanced breast cancer after failure of prior therapy;							
Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;							
Locally advanced or metastatic non-small cell lung cancer.							
<b>Authority required</b>							
Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.							

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<b>Note</b>							
A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.							
<b>Note</b>							
The 20 mg solution concentrates for I.V. infusion and solution for I.V. infusion (after reconstitution) are bioequivalent.							
5855E	Solution concentrate for I.V. infusion 20 mg in 1 mL	2	..	..	*576.58	34.20 <sup>a</sup>	Oncotaxel 20 TA
							<sup>a</sup> Taxotere SW
5860K	Solution concentrate for I.V. infusion 20 mg in 2 mL	2	..	..	*576.58	34.20 <sup>a</sup>	DBL Docetaxel Concentrated Injection HH
							<sup>a</sup> Docetaxel Ebewe HX
5921P	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	2	..	..	*576.58	34.20 <sup>a</sup>	Taxotere SW
<b>NAB PACLITAXEL</b>							
<b>Authority required</b>							
Metastatic breast cancer after failure of prior therapy.							
5847R	Powder for I.V. injection 100 mg (base)	1	..	..	401.48	34.20	Abraxane TS
<b>PACLITAXEL</b>							
<b>Authority required</b>							
Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide;							
Advanced breast cancer after failure of prior therapy;							
Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound;							
Primary treatment of ovarian cancer in combination with a platinum compound;							
Locally advanced or metastatic non-small cell lung cancer;							
Treatment of HER2 positive early breast cancer in combination with trastuzumab.							
5973J	Solution concentrate for I.V. infusion 30 mg in 5 mL	5	..	..	*392.45	34.20 <sup>a</sup>	Anzatax HH
							<sup>a</sup> Paclitaxel Actavis GQ
							<sup>a</sup> Paclitaxel Kabi PK
							<sup>a</sup> Plaxel WQ
							<sup>a</sup> Taxol BQ
				..	392.48	34.20 <sup>a</sup>	Paclitaxel Ebewe SZ
5974K	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	2	..	..	*520.74	34.20 <sup>a</sup>	Anzatax HH
							<sup>a</sup> Paclitaxel Actavis GQ
							<sup>a</sup> Paclitaxel Ebewe SZ
							<sup>a</sup> Paclitaxel Kabi PK
							<sup>a</sup> Plaxel WQ
							<sup>a</sup> Taxol BQ
5975L	Solution concentrate for I.V. infusion 150 mg in 25 mL	2	..	..	*759.04	34.20 <sup>a</sup>	Anzatax HH
							<sup>a</sup> Paclitaxel Actavis GQ
							<sup>a</sup> Paclitaxel Ebewe SZ
							<sup>a</sup> Plaxel WQ
5976M	Solution concentrate for I.V. infusion 300 mg in 50 mL	1	..	..	790.88	34.20 <sup>a</sup>	Anzatax HH
							<sup>a</sup> Paclitaxel Actavis GQ
							<sup>a</sup> Paclitaxel Ebewe SZ
							<sup>a</sup> Paclitaxel Kabi PK
							<sup>a</sup> Plaxel WQ
							<sup>a</sup> Taxol BQ

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	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 HYDROCHLORIDE</b>								
5879K	Solution for I.V. injection or intravesical administration 100 mg in 50 mL	1	..	..	58.14	34.20	Doxorubicin Ebewe	SZ
5880L	Solution for I.V. injection or intravesical administration 200 mg in 100 mL	1	..	..	116.27	34.20	<sup>a</sup> Adriamycin	PF
							<sup>a</sup> Doxorubicin Ebewe	SZ
5925W	Solution for I.V. injection or intravesical administration 10 mg in 5 mL	4	..	..	*27.52	28.59	<sup>a</sup> Adriamycin Solution	PF
							<sup>a</sup> Doxorubicin Ebewe	SZ
							<sup>a</sup> Hospira Pty Limited	HH
5926X	Solution for I.V. injection or intravesical administration 20 mg in 10 mL	4	..	..	*49.20	34.20	Adriamycin Solution	PF
5927Y	Solution for I.V. injection or intravesical administration 50 mg in 25 mL	3	..	..	*87.21	34.20	<sup>a</sup> Adriamycin Solution	PF
							<sup>a</sup> Doxorubicin Ebewe	SZ
							<sup>a</sup> Hospira Pty Limited	HH
<b>DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL</b>								
<b><u>Authority required</u></b>								
Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen;								
Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane;								
Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated.								
5891C	Suspension for I.V. infusion 20 mg in 10 mL	1	..	..	622.99	34.20	Caelyx	JC
5892D	Suspension for I.V. infusion 50 mg in 25 mL	1	..	..	1483.30	34.20	Caelyx	JC
<b>EPIRUBICIN HYDROCHLORIDE</b>								
5884Q	Solution for injection 200 mg in 100 mL	1	..	..	666.26	34.20	<sup>a</sup> DBL Epirubicin Hydrochloride Injection	HH
							<sup>a</sup> Epirubicin Ebewe	SZ
5885R	Solution for injection 100 mg in 50 mL	2	..	..	*676.40	34.20	<sup>a</sup> Epirubicin Ebewe <sup>a</sup> Hospira Pty Limited	SZ HH
5928B	Solution for injection 10 mg in 5 mL	4	..	..	*143.64	34.20	<sup>a</sup> Epirubicin Ebewe <sup>a</sup> Pharmorubicin Solution	SZ PF
5929C	Solution for injection 20 mg in 10 mL	4	..	..	*277.24	34.20	Pharmorubicin Solution	PF
5930D	Solution for injection 50 mg in 25 mL	4	..	..	*685.60	34.20	<sup>a</sup> Epirubicin Ebewe <sup>a</sup> Hospira Pty Limited	SZ HH
							<sup>a</sup> Pharmorubicin Solution	PF
<b>IDARUBICIN HYDROCHLORIDE</b>								
<b><u>Restricted benefit</u></b>								
Acute myelogenous leukaemia.								
5941Q	Solution for I.V. injection 5 mg in 5 mL	3	..	..	*422.52	34.20	<sup>a</sup> Idarubicin Ebewe	SZ
					422.53	34.20	<sup>a</sup> Zavedos Solution	PF
5942R	Solution for I.V. injection 10 mg in 10 mL	6	..	..	*1633.86	34.20	<sup>a</sup> Idarubicin Ebewe	SZ
					1633.90	34.20	<sup>a</sup> Zavedos Solution	PF
<b>MITOZANTRONE HYDROCHLORIDE</b>								
5964X	Injection 10 mg (base) in 5 mL	1	..	..	73.00	34.20	Pfizer Australia Pty Ltd	PF
5965Y	Injection 20 mg (base) in 10 mL	1	..	..	146.00	34.20	<sup>a</sup> Hospira Pty Limited <sup>a</sup> Mitozantrone Ebewe	HH SZ

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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					for Max. Qty \$	Recordable Value for Safety Net \$			
5966B	Injection 25 mg (base) in 12.5 mL	1	..	..	182.40	34.20	a	Onkotrone	BX
							a	Pfizer Australia Pty Ltd	PF
							a	Onkotrone	BX
							a	Pfizer Australia Pty Ltd	PF

### Other antineoplastic agents *Platinum compounds*

#### CARBOPLATIN

5906W	Solution for I.V. injection 50 mg in 5 mL	2	..	..	*49.26	34.20	a	Carboplatin Ebewe	SZ
							a	Hospira Pty Limited	HH
							a	Pfizer Australia Pty Ltd	PF
5907X	Solution for I.V. injection 150 mg in 15 mL	6	..	..	*356.76	34.20	a	Carboplatin Ebewe	SZ
							a	Hospira Pty Limited	HH
							a	Pfizer Australia Pty Ltd	PF
5908Y	Solution for I.V. injection 450 mg in 45 mL	2	..	..	*224.06	34.20	a	Carboplatin Ebewe	SZ
							a	Hospira Pty Limited	HH
							a	Pfizer Australia Pty Ltd	PF

#### CISPLATIN

5909B	I.V. injection 10 mg in 10 mL	1	..	..	3.99	5.50		Pfizer Australia Pty Ltd	PF
5910C	I.V. injection 50 mg in 50 mL	1	..	..	10.71	11.78	a	Hospira Pty Limited	HH
							a	Pfizer Australia Pty Ltd	PF
5911D	I.V. injection 100 mg in 100 mL	1	..	..	26.98	28.05	a	Cisplatin Ebewe	SZ
							a	Hospira Pty Limited	HH
							a	Pfizer Australia Pty Ltd	PF

#### OXALIPLATIN

##### Authority required

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

(a) capecitabine; or

(b) 5-fluorouracil and folinic acid;

Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with 5-fluorouracil and folinic acid, following complete resection of the primary tumour.

##### Note

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

Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

##### Note

The solution concentrate for I.V. infusion 50 mg and powder for I.V. infusion 50 mg (after reconstitution) are bioequivalent.

5877H	Solution concentrate for I.V. infusion 50 mg in 10 mL	1	2	..	303.10	34.20	a	DBL Oxaliplatin Concentrate	HH
							a	Eloxatin	SW
							a	Oxaliplatin Kabi	PK
5994L	Powder for I.V. infusion 50 mg	1	2	..	303.10	34.20	a	Hospira Pty Limited	HH
							a	Oxalatin	ZP
							a	Oxaliplatin Actavis	GQ
							a	Oxaliplatin Alphapharm	AF
							a	Oxaliplatin Ebewe	SZ
							a	Oxaliplatin Link	PK
a	Xalox	WQ							

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>OXALIPLATIN</b>								
<b><u>Authority required</u></b>								
Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with:								
(a) capecitabine; or								
(b) 5-fluorouracil and folinic acid;								
Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with 5-fluorouracil and folinic acid, following complete resection of the primary tumour.								
<b><u>Note</u></b>								
Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.								
Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.								
<b><u>Note</u></b>								
The solution concentrate for I.V. infusion 100 mg and powder for I.V. infusion 100 mg (after reconstitution) are bioequivalent.								
5878J	Solution concentrate for I.V. infusion 100 mg in 20 mL	1	2	..	585.48	34.20	<sup>a</sup> DBL Oxaliplatin Concentrate <sup>a</sup> Eloxatin <sup>a</sup> Oxaliplatin Kabi	HH SW PK
5995M	Powder for I.V. infusion 100 mg	1	2	..	585.48	34.20	<sup>a</sup> Hospira Pty Limited <sup>a</sup> Oxalatin <sup>a</sup> Oxaliplatin Actavis <sup>a</sup> Oxaliplatin Alphapharm <sup>a</sup> Oxaliplatin Ebewe <sup>a</sup> Oxaliplatin Link <sup>a</sup> Winthrop <sup>a</sup> Oxaliplatin Xalox	HH ZP GQ AF SZ PK WA WQ

### OXALIPLATIN

#### **Authority required**

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

(a) capecitabine; or

(b) 5-fluorouracil and folinic acid;

Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with 5-fluorouracil and folinic acid, following complete resection of the primary tumour.

#### **Note**

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

Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

5999R	Solution concentrate for I.V. infusion 200 mg in 40 mL	1	2	..	1165.56	34.20	Eloxatin	SW
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### ***Monoclonal antibodies***

#### BEVACIZUMAB

#### **Authority required**

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

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

#### **Note**

Not for use as monotherapy.

#### **Authority required**

Continuing PBS-subsidised treatment, in combination with first-line chemotherapy, of a patient with metastatic colorectal cancer who has previously been issued with an authority prescription for bevacizumab and who does not have progressive disease and who remains on first-line chemotherapy. The maximum dose that will be approved is 5 mg per kg every 2 weeks or 7.5 mg per kg every 3 weeks.

#### **Note**

Not for use as monotherapy.

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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

**Note**

Special Pricing Arrangements apply.

5849W	Solution for I.V. infusion 100 mg in 4 mL	1	..	..	472.50	34.20	Avastin	RO
5850X	Solution for I.V. infusion 400 mg in 16 mL	1	..	..	1720.00	34.20	Avastin	RO

**CETUXIMAB****Authority required**

Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the TGA-approved Product Information;

Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated.

**Note**

No applications for repeats will be authorised.

5836E	Solution for I.V. infusion 100 mg in 20 mL	1	..	..	341.00	34.20	Erbix	SG
5837F	Solution for I.V. infusion 500 mg in 100 mL	1	..	..	1705.00	34.20	Erbix	SG

**CETUXIMAB****Authority required**

Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated.

**Note**

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

5838G	Solution for I.V. infusion 100 mg in 20 mL	1	6	..	341.00	34.20	Erbix	SG
5839H	Solution for I.V. infusion 500 mg in 100 mL	1	6	..	1705.00	34.20	Erbix	SG

**RITUXIMAB****Authority required**

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

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

5978P	Solution for I.V. infusion 100 mg in 10 mL	2	3	..	905.43	34.20	Mabthera	RO
5979Q	Solution for I.V. infusion 500 mg in 50 mL	1	3	..	2263.57	34.20	Mabthera	RO

**RITUXIMAB****Authority required**

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

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

5896H	Solution for I.V. infusion 100 mg in 10 mL	2	7	..	905.43	34.20	Mabthera	RO
5897J	Solution for I.V. infusion 500 mg in 50 mL	1	7	..	2263.57	34.20	Mabthera	RO

### Other antineoplastic agents

**ARSENIC TRIOXIDE****Authority required**

Induction and consolidation treatment of relapsed acute promyelocytic leukaemia (characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript) in a patient who is arsenic naive at induction.

5851Y	Injection concentrate 10 mg in 10 mL	60	2	..	*24049.62	34.20	Phenasen	PL
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**IRINOTECAN HYDROCHLORIDE TRIHYDRATE****Authority required (STREAMLINED)**

3184

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

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		Brand Name and Manufacturer	
	<b>Note</b> In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.								
5833B	I.V. injection 500 mg in 25 mL	1	3	..	549.75	34.20	<sup>a</sup>	Hospira Pty Limited	HH
							<sup>a</sup>	Irinotecan Ebewe	SZ
5846Q	I.V. injection 300 mg in 15 mL	1	3	..	321.58	34.20	<sup>a</sup>	Camptosar	PF
							<sup>a</sup>	Irinotecan Ebewe	SZ
5958N	I.V. injection 40 mg in 2 mL	1	3	..	42.92	34.20	<sup>a</sup>	Camptosar	PF
							<sup>a</sup>	Hospira Pty Limited	HH
							<sup>a</sup>	Irinotecan Actavis	GQ
							<sup>a</sup>	Irinotecan Alphapharm	AF
							<sup>a</sup>	Irinotecan Ebewe	SZ
							<sup>a</sup>	Omegapharm Irinotecan	OE
							<sup>a</sup>	Tecan	WQ
5959P	I.V. injection 100 mg in 5 mL	2	3	..	*214.58	34.20	<sup>a</sup>	Camptosar	PF
							<sup>a</sup>	Hospira Pty Limited	HH
							<sup>a</sup>	Irinotecan Actavis	GQ
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							<sup>a</sup>	Irinotecan Ebewe	SZ
							<sup>a</sup>	Omegapharm Irinotecan	OE
							<sup>a</sup>	Tecan	WQ

### TOPOTECAN HYDROCHLORIDE

#### Authority required (STREAMLINED)

3186

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

5985B	Powder for I.V. infusion 4 mg (base)	5	1	..	1980.00	34.20		Hycamtin	GK
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## 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

Hairy cell leukaemia;

Myeloproliferative disease with excessive thrombocytosis.

5945X	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	4	..	*447.00	34.20		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

Myeloproliferative disease with excessive thrombocytosis.

5996N	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*223.50	34.20		Roferon-A	RO
5997P	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*297.90	34.20		Roferon-A	RO
5998Q	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	4	..	*446.90	34.20		Roferon-A	RO

## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty	No. of Rpts	Premium	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>INTERFERON ALFA-2a</b>								
<b>Caution</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>Authority required</b>								
Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy.								
5946Y	Injection 3,000,000 i.u. in 0.5 mL single dose pre-filled syringe	15	5	..	*447.00	34.20	Roferon-A	RO
5947B	Injection 4,500,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*223.50	34.20	Roferon-A	RO
5948C	Injection 6,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*297.90	34.20	Roferon-A	RO
5949D	Injection 9,000,000 i.u. in 0.5 mL single dose pre-filled syringe	5	5	..	*446.90	34.20	Roferon-A	RO

### INTERFERON ALFA-2b

#### Caution

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

#### Authority required

Hairy cell leukaemia.

5893E	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	3	4	..	*536.22	34.20	Intron A Redipen	MK
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### INTERFERON ALFA-2b

#### Caution

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

#### Authority required

Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy;

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

5953H	Solution for injection 18,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	*536.22	34.20	Intron A Redipen	MK
5956L	Solution for injection 30,000,000 i.u. in 1.2 mL multi-dose injection pen	3	5	..	*893.70	34.20	Intron A Redipen	MK

## Other immunostimulants

### BCG IMMUNOTHERAPEUTIC (Bacillus Calmette-Guérin/ Connaught strain)

#### Restricted benefit

Treatment of carcinoma in situ of the urinary bladder.

5901N	Powder for intravesical administration containing 6.6 to 19.2 x 10 <sup>8</sup> CFU	3	1	..	*405.00	34.20	ImmuCyst	SW
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### BCG-TICE (Bacillus Calmette-Guérin/ Tice strain)

#### Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder.

5902P	Vial containing powder for intravesical administration approximately 5 x 10 <sup>8</sup> CFU	3	1	..	491.83	34.20	OncoTICE	MK
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## CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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

#### All other therapeutic products

#### All other therapeutic products

#### *Detoxifying agents for antineoplastic treatment*

##### CALCIUM FOLINATE

5863N	Injection equivalent to 1000 mg folinic acid in 100 mL	1	1	..	217.91	34.20	Calcium Folate Ebewe	SZ
5870Y	Injection equivalent to 300 mg folinic acid in 30 mL	4	1	..	*254.92	34.20	<sup>a</sup> Calcium Folate Ebewe	SZ
							<sup>a</sup> Leucovorin Calcium (Hospira Pty Limited)	HH
5886T	Injection equivalent to 100 mg folinic acid in 10 mL	10	1	..	*217.90	34.20	<sup>a</sup> Calcium Folate Ebewe	SZ
				..	217.97	34.20	<sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
5890B	Injection equivalent to 50 mg folinic acid in 5 mL	5	5	..	*118.05	34.20	<sup>a</sup> Leucovorin Calcium (Hospira Pty Limited)	HH
				..	118.10	34.20	<sup>a</sup> Calcium Folate Ebewe	SZ
				..	*118.23	34.20	<sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF

##### CALCIUM FOLINATE

##### Restricted benefit

Antidote to folic acid antagonists.

5904R	Tablet equivalent to 15 mg folinic acid	10	..	..	76.00	34.20	Leucovorin Calcium (Hospira Pty Limited)	HH
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##### MESNA

##### Restricted benefit

Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide.

5960Q	Solution for I.V. injection 400 mg in 4 mL	15	5	..	81.89	34.20	Uromitexan	BX
5961R	Solution for I.V. injection 1 g in 10 mL	15	5	..	185.44	34.20	Uromitexan	BX

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