



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

**EFFECTIVE 1 December 2011 -
31 December 2011
(ALL PREVIOUS EDITIONS CANCELLED)**

SUMMARY OF CHANGES

New prescribing and dispensing arrangements for certain chemotherapy drugs covered by CPAP will take effect from 1 December 2011 under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs (please refer to the Explanatory Notes on page 4 for more details).

Additions

Addition – Item

- 5589E **Rituximab**, Solution for I.V. infusion 100 mg in 10 mL (*Mabthera*)
 5590F **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL (*Mabthera*)

Addition – Caution

The following caution has been applied to all Docetaxel items:

CAUTION

Pharmaceutical benefits containing docetaxel may have different concentrations.

Deletions

Deletion – Item

- 5984Y **Thiotepa**, Powder for injection 15 mg (*Aspen Pharma Pty Ltd*)

Alterations

Alteration – Restriction

- 5994L **Oxaliplatin**, Powder for I.V. infusion 50 mg (*Hospira Pty Limited, Oxaliplatin Ebewe, Oxalatin, Oxaliplatin Actavis, Oxaliplatin Alphapharm, Oxaliplatin Link, Xalox*)
 5995M **Oxaliplatin**, Powder for I.V. infusion 100 mg (*Hospira Pty Limited, Oxaliplatin Ebewe, Winthrop Oxaliplatin, Oxalatin, Oxaliplatin Actavis, Oxaliplatin Alphapharm, Oxaliplatin Link, Xalox*)
 5877H **Oxaliplatin**, Solution concentrate for I.V. infusion 50 mg in 10 mL (*Eloxatin, DBL Oxaliplatin Concentrate, Oxaliplatin Kabi, Oxaliplatin SUN*)
 5878J **Oxaliplatin**, Solution concentrate for I.V. infusion 100 mg in 20 mL (*Eloxatin, DBL Oxaliplatin Concentrate, Oxaliplatin Kabi, Oxaliplatin SUN*)
 5999R **Oxaliplatin**, Solution concentrate for I.V. infusion 200 mg in 40 mL (*Eloxatin, Oxaliplatin SUN*)

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.

Revised Arrangements for the Efficient Funding of Chemotherapy Drugs

New prescribing and dispensing arrangements for certain chemotherapy drugs covered by Chemotherapy Pharmaceuticals Access Program (CPAP) will take effect from 1 December 2011 under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs (Revised Arrangements).

The Revised Arrangements will operate under a new section 100 program, which will include chemotherapy drugs used for the treatment of cancer and administered through infusion or injection. A separate "EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS" schedule provides the listing details for these items. The schedule, in PDF format, will be available on the PBS website, www.pbs.gov.au/browse/publications from 1 December 2011.

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

- Where public hospitals have moved to the Revised Arrangements, they will need to comply with the new guidelines for writing prescriptions (please refer to the new "EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS" schedule for details).
- Where public hospitals have NOT moved to the Revised Arrangements they can continue to use the existing CPAP S100 arrangements that currently apply for chemotherapy infusibles.
- Where public hospitals write prescriptions for chemotherapy infusibles, that are to be dispensed outside public hospitals, they will need to comply with the new guidelines for writing prescriptions (please refer to the new "EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS" schedule for details).

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 | LY | Eli Lilly Australia Pty Limited 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444 Fax: (02) 9325 4410 |
| AF | Alphapharm Pty Limited Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Tel: (02) 9298 3999 Fax: (02) 9566 4686 | MK | Merck Sharp & Dohme (Australia) Pty Ltd 54-68 Ferndell Street South Granville NSW 2142 Tel: (02) 9795 9500 Fax: (02) 9795 9595 |
| 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 | NV | Novartis Pharmaceuticals Australia Pty Ltd 54 Waterloo Road North Ryde NSW 2113 Tel: (02) 9805 3555 Fax: (02) 9887 4551 |
| BX | Baxter Healthcare Pty Limited 1 Baxter Drive Old Toongabbie NSW 2146 Tel: (02) 9848 1111 Fax: (02) 9848 1123 | OA | Orphan Australia Pty Ltd A member of Aspen Group of Companies First Floor, 34-36 Chandos Street St Leonards NSW 2065 Tel: (02) 8436 8300 Fax: (02) 9901 3540 |
| 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 | OE | Omegapharm Pty Ltd 21 Queen Street Ormond Vic 3204 Tel: (03) 9483 0070 Fax: (03) 9483 0070 |
| GK | GlaxoSmithKline Australia Pty Ltd Level 4, 436-438 Johnston Street Abbotsford Vic 3067 Tel: (03) 9413 7300 Fax: (03) 8761 2410 | PF | Pfizer Pty Limited 38-42 Wharf Road West Ryde NSW 2114 Tel: (02) 9850 3333 Fax: (02) 9858 1347 |
| 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 | PK | Fresenius Kabi Australia Pty Limited 964 Pacific Highway Pymble NSW 2073 Tel: 1300 732 001 Fax: 1300 304 384 |
| HH | Hospira Pty Ltd (David Bull Laboratories, Faulding Pharmaceuticals) Level 3, 500 Collins Street Melbourne Vic 3000 Tel: (03) 8744 5200 Fax: (03) 9866 3504 | PL | Phebra 332 Burns Bay Road Lane Cove NSW 2066 Tel: (02) 9420 9199 Fax: (02) 9420 9177 |
| HX | Hexal Australia A division of Sandoz Pty Ltd Level 4, Suite 7-19 100 Harris Street Pyrmont NSW 2009 Tel: (02) 9566 1500 Fax: (02) 9566 1458 | RO | Roche Products Pty Ltd 4-10 Inman Road Dee Why NSW 2099 Tel: (02) 9454 9000 Fax: (02) 9971 7401 |
| JC | Janssen-Cilag Pty Ltd 1-5 Khartoum Road North Ryde NSW 2113 Tel: (02) 8875 3333 Fax: (02) 8875 3300 | RZ | Dr Reddy's Laboratories (Australia) Pty Ltd Level 1, 181 Bay Street Brighton Vic 3186 Tel: (03) 9595 3812 Fax: (03) 9595 3800 |
| | | SE | Servier Laboratories (Aust.) Pty Ltd 8 Cato Street Hawthorn Vic 3122 Tel: (03) 8823 7333 Fax: (03) 9822 9790 |

Index of Manufacturers' Codes

| <i>Code</i> | <i>Manufacturer</i> | <i>Code</i> | <i>Manufacturer</i> |
|-------------|--|-------------|---------------------|
| 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 | | |
| 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 | | |
| TA | Actavis Australia Pty Ltd Upper Ground Floor 183 Melbourne Street North Adelaide SA 5006 Tel: (08) 8267 1545 Fax: (08) 8267 2642 | | |
| TS | Specialised Therapeutics Australia Pty Ltd Level 1, 711 High Street Kew East Vic 3102 Tel: 1300 798 820 Fax: 1800 798 829 | | |
| TX | Apotex Pty Ltd 16 Giffnock Avenue Macquarie Park NSW 2113 Tel: (02) 8877 8333 Fax: (02) 8877 8377 | | |
| 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 | | |
| WQ | Willow Pharmaceuticals Pty Limited Level 4, 5 Essex Street The Rocks NSW 2000 Tel: (02) 9241 2235 Fax: (02) 9241 2217 | | |
| ZF | Sun Pharmaceutical Industries (Australia) Pty Ltd 1053 Burwood Highway Ferntree Gully Vic 3156 Tel: (03) 9568 6102 Fax: (03) 9568 6610 | | |
| ZP | Spirit Pharmaceuticals Pty Ltd 117 Harrington Street The Rocks Sydney NSW 2000 Tel: (02) 9251 1088 Fax: (02) 9251 1099 | | |

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 |
|------|---|-------------|----------------|---------|--|--|--|-----------------------------|
|------|---|-------------|----------------|---------|--|--|--|-----------------------------|

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 |
|-------|----------------------------------|----|----|----------|---------|---------|-------|---------------------|----|

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 |
|------|---|-------------|-------------|---------|--|--|-----------------------------|
|------|---|-------------|-------------|---------|--|--|-----------------------------|

Alimentary tract and metabolism

Antiemetics and antinauseants

Antiemetics and antinauseants *Serotonin (5HT₃) antagonists*

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 | 26.51 | ^a Kytril | HH |
| | | | | | *26.51 | 27.60 | ^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

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 | Tablet (orally disintegrating) 4 mg | 4 | .. | .. | 16.17 | 17.26 | ^a Ondansetron ODT- DRLA | RZ |
| 5969E | Wafer 4 mg | 4 | .. | .. | 16.17 | 17.26 | ^a Ondaz Zydis ^a Zofran Zydis | SZ GK |

ONDANSETRON

Restricted benefit

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

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

Note

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

| | | | | | | | | |
|-------|-------------------------------------|---|----|----|-------|-------|---|----------|
| 5858H | Tablet (orally disintegrating) 8 mg | 4 | .. | .. | 25.33 | 26.42 | ^a Ondansetron ODT-DRLA | RZ |
| 5970F | Wafer 8 mg | 4 | .. | .. | 25.33 | 26.42 | ^a Ondaz Zydis ^a Zofran Zydis | SZ 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.

| | | | | | | | | |
|-------|--|---|----|----|-------|-------|---|----------------|
| 5848T | Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. 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 | .. | .. | 16.17 | 17.26 | ^a APO-Ondansetron TX ^a Ondansetron-DRLA ^a Ondaz ^a Onsetron 4 | RZ SZ ZP |

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 | | |
|-------|---|-------------|-------------|---------|--|--|-----------------------------|-----------------------------|----|
| 5968D | Tablet 8 mg (as hydrochloride dihydrate) | 4 | .. | .. | 25.33 | 26.42 | a | Zofran | GK |
| | | | | | | | a | APO-Ondansetron | TX |
| | | | | | | | a | Ondansetron-DRLA | RZ |
| | | | | | | | a | Ondaz | SZ |
| | | | | | | | a | Onsetron 8 | ZP |
| 5971G | I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL | 1 | .. | .. | 8.47 | 9.56 | a | Zofran | GK |
| | | | | | | | a | Ondansetron | AF |
| | | | | | | | a | Alphapharm | |
| | | | | | | | a | Ondansetron-Claris | AE |
| | | | | | | | a | Ondaz | SZ |
| 5972H | I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL | 1 | .. | .. | 13.46 | 14.55 | a | Onsetron | ZP |
| | | | | | | | a | Pfizer Australia Pty Ltd | PF |
| | | | | | | | a | Zofran | GK |
| | | | | | | | a | Ondansetron | AF |
| | | | | | | | a | Alphapharm | |
| | | | | | | | a | Ondansetron-Claris | AE |
| | | | | | | | a | Ondaz | SZ |
| | | | | | | | a | Onsetron | ZP |
| | | | | | | | a | Pfizer Australia Pty Ltd | PF |
| | | | | | | | a | Zofran | GK |

PALONOSETRON

Restricted benefit

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

Note

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

| | | | | | | | | |
|-------|--|---|----|----|-------|-------|-------|----|
| 5853C | Injection 250 micrograms (as hydrochloride) in 5 mL | 1 | .. | .. | 34.36 | 34.20 | Aloxi | TS |
|-------|--|---|----|----|-------|-------|-------|----|

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 | 19.59 | 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;

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 |
|-------|--|-------------|-------------|---------|--|--|-----------------------------|
| | <p>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;</p> | | | | | | |
| | <p>3621 Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered:</p> <ul style="list-style-type: none"> (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. <p>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.</p> | | | | | | |
| | <p>Note No applications for increased maximum quantities and/or repeats will be authorised.</p> | | | | | | |
| 5888X | Pack containing 1 capsule 125 mg and 2 capsules 80 mg | #1 | 5 | .. | 112.01 | 34.20 | Emend MK |

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 \$ | |

Antineoplastic and immunomodulating agents

Antineoplastic agents

Alkylating agents

Nitrogen mustard analogues

CYCLOPHOSPHAMIDE

| | | | | | | | | |
|-------|-----------------------------|---|----|----|--------|-------|---------|----|
| 5914G | Powder for injection 500 mg | 2 | .. | .. | *27.72 | 28.81 | Endoxan | BX |
| 5915H | Powder for injection 1 g | 1 | .. | .. | 21.21 | 22.30 | 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 |

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 |
|-------|--|---|---|----|---------|-------|----------|----|

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 | ^a Hospira Pty Limited | HH |
| | | | | | | | ^a 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 | 25.18 | Hospira Pty Limited | HH |
| 5963W | Injection 50 mg in 2 mL | 5 | 5 | .. | 23.54 | 24.63 | ^a Hospira Pty Limited ^a Pfizer Australia Pty Ltd | HH PF |

PEMETREXED DISODIUM

Authority required (STREAMLINED)

3885

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

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

Authority required (STREAMLINED)

3886

Mesothelioma in combination with cisplatin.

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

Note

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

| | | | | | | | | |
|-------|--|---|---|----|---------|-------|--------|----|
| 5834C | Powder for I.V. infusion 500 mg (base) | 1 | 3 | .. | 1559.86 | 34.20 | Alimta | LY |
|-------|--|---|---|----|---------|-------|--------|----|

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 \$ | | |
| 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 |
|-------|-------------------------------|---|---|----|---------|-------|---------|----|

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 (STREAMLINED)

3887

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

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

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

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

Note

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

| | | | | | | | | |
|-------|---|---|---|----|----------|-------|----------------------------------|----|
| 5840J | Powder for I.V. injection 50 mg | 5 | 3 | .. | 1371.22 | 34.20 | ^a Fludara | GZ |
| | | | | | *1371.25 | 34.20 | ^a Farine | WQ |
| 5841K | Solution for I.V. injection 50 mg in 2 mL | 5 | 3 | .. | 1371.22 | 34.20 | ^a Fludarabine Actavis | TA |
| | | | | | | | ^a Fludarabine Ebewe | SZ |

Pyrimidine analogues

CYTARABINE

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

FLUOROURACIL

| | | | | | | | | |
|-------|-----------------------------|----|----|----|--------|-------|--|----|
| 5807P | Injection 2500 mg in 50 mL | 2 | .. | .. | *34.70 | 34.20 | ^a DBL Fluorouracil Injection BP | HH |
| | | | | | | | ^a 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 | .. | .. | 34.69 | 34.20 | ^a DBL Fluorouracil Injection BP | HH |
| | | | | | | | ^a Fluorouracil Ebewe | SZ |
| 5935J | Injection 500 mg in 10 mL | 10 | .. | .. | *40.82 | 34.20 | ^a Fluorouracil Ebewe | SZ |
| | | | | | | | ^a Hospira Pty Limited | HH |

GEMCITABINE

Authority required (STREAMLINED)

3913

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

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 \$ | | | |
| | 3914 Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy; | | | | | | | | |
| | 3890 Locally advanced or metastatic non-small cell lung cancer; | | | | | | | | |
| | 3889 Locally advanced or metastatic adenocarcinoma of the pancreas; | | | | | | | | |
| | 3906 Locally advanced or metastatic bladder cancer, in combination with cisplatin. | | | | | | | | |
| | Note Pharmaceutical benefits that have the form gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) are equivalent for the purposes of substitution. | | | | | | | | |
| 5843M | Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL | 4 | 2 | .. | *106.28 | 34.20 | ^a | Gemcitabine Ebewe | SZ |
| 5936K | Powder for I.V. infusion 200 mg (as hydrochloride) | 4 | 2 | .. | *106.28 | 34.20 | ^a | DBL Gemcitabine for Injection | HH |
| | | | | | | | ^a | Gemcitabine Actavis | TA |
| | | | | | | | ^a | Gemcitabine Ebewe | SZ |
| | | | | | | | ^a | Gemcitabine Kabi | PK |
| | | | | | | | ^a | Gemcitabine Sun | ZF |
| | | | | | | | ^a | Gemcite | ZP |
| | | | | | | | ^a | Gemplan | WQ |
| | | | | | | | ^a | Gemzar | LY |

GEMCITABINE

Authority required (STREAMLINED)

3913

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

3914

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

3890

Locally advanced or metastatic non-small cell lung cancer;

3889

Locally advanced or metastatic adenocarcinoma of the pancreas;

3906

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

Note

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

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

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 | |
|---|---|-------------|-------------|---------|--|--|--|----------|
| GEMCITABINE | | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | | |
| 3913 | | | | | | | | |
| Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline; | | | | | | | | |
| 3914 | | | | | | | | |
| Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy; | | | | | | | | |
| 3890 | | | | | | | | |
| Locally advanced or metastatic non-small cell lung cancer; | | | | | | | | |
| 3889 | | | | | | | | |
| Locally advanced or metastatic adenocarcinoma of the pancreas; | | | | | | | | |
| 3906 | | | | | | | | |
| 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 ^a | DBL Gemcitabine for Injection Gemcitabine Kabi | HH PK |
| 5852B | Solution concentrate for I.V. infusion 500 mg (as hydrochloride) in 50 mL | 4 | 2 | .. | *262.44 | 34.20 | Gemcitabine Ebewe | SZ |

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

| | | | | | | | | |
|--|--|----|----|----|----------|--------------------|---|----------------------|
| VINBLASTINE SULFATE | | | | | | | | |
| 5989F | Solution for I.V. injection 10 mg in 10 mL | 5 | .. | .. | 138.12 | 34.20 | Hospira Pty Limited | HH |
| VINCRIStINE SULFATE | | | | | | | | |
| 5991H | I.V. injection 1 mg in 1 mL | 10 | .. | .. | *123.28 | 34.20 ^a | Hospira Pty Limited Pfizer Australia Pty Ltd | HH PF |
| VINORELBINE | | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | | |
| 3907 | | | | | | | | |
| Advanced breast cancer after failure of prior therapy which includes an anthracycline; | | | | | | | | |
| 3890 | | | | | | | | |
| 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 ^a | Hospira Pty Limited Navelbine Vinorelbine Ebewe | HH FB SZ |
| 5993K | Solution for I.V. infusion 50 mg (as tartrate) in 5 mL | 4 | 2 | .. | *1041.60 | 34.20 ^a | Hospira Pty Limited Navelbine Vinorelbine Ebewe Vinorelbine Kabi | HH FB SZ PK |

Podophyllotoxin derivatives

| | | | | | | | | |
|------------------|--|---|----|----|---------|--------------------|---------------------|----|
| ETOPOSIDE | | | | | | | | |
| 5931E | Solution for I.V. infusion 100 mg in 5 mL | 5 | .. | .. | 132.80 | 34.20 ^a | Etoposide Ebewe | SZ |
| | | | | .. | *132.80 | 34.20 ^a | 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 |

Taxanes

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

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 \$ | |
| <u>Authority required (STREAMLINED)</u> | | | | | | | |
| 3888 | | | | | | | |
| Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil. | | | | | | | |
| Note | | | | | | | |
| The carcinoma can be considered inoperable for technical or organ preservation reasons. | | | | | | | |
| Note | | | | | | | |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. | | | | | | | |
| 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 ^a | Taxotere SW |
| 5854D | Solution concentrate for I.V. infusion 20 mg in 1 mL | 1 | .. | .. | 288.29 | 34.20 ^a | Oncotaxel 20 TA |
| | | | | | | | ^a Taxotere SW |
| 5859J | Solution concentrate for I.V. infusion 20 mg in 2 mL | 1 | .. | .. | 288.29 | 34.20 ^a | DBL Docetaxel Concentrated Injection HH |
| | | | | | | | ^a Docetaxel Ebewe HX |
| | | | | | | | ^a Docetaxel Sandoz SZ |

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3888

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

Note

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

Authority required (STREAMLINED)

3916

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

3893

Advanced breast cancer after failure of prior therapy;

3186

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

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority required (STREAMLINED)

3884

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

Note

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

| | | | | | | | |
|-------|--|---|----|----|---------|-------|---|
| 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

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3918

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

CHEMOTHERAPY 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 |
|--|---|-------------|-------------|---------|--|--|--|
| Note | | | | | | | |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. | | | | | | | |
| 5864P | Solution concentrate for I.V. infusion 20 mg in 1 mL | 2 | .. | .. | *576.58 | 34.20 ^a | Oncotaxel 20 TA |
| | | | | | | | ^a Taxotere SW |
| 5865Q | Solution concentrate for I.V. infusion 20 mg in 2 mL | 2 | .. | .. | *576.58 | 34.20 ^a | DBL Docetaxel Concentrated Injection HH |
| | | | | | | | ^a Docetaxel Sandoz SZ |
| 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 ^a | Taxotere SW |
| <hr/> | | | | | | | |
| DOCETAXEL | | | | | | | |
| Caution | | | | | | | |
| Pharmaceutical benefits containing docetaxel may have different concentrations. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3918 | | | | | | | |
| Treatment of HER2 positive early breast cancer in combination with trastuzumab. | | | | | | | |
| Note | | | | | | | |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. | | | | | | | |
| 5867T | Solution concentrate for I.V. infusion 80 mg in 4 mL | 1 | .. | .. | 1155.45 | 34.20 ^a | Oncotaxel 80 TA |
| | | | | | | | ^a Taxotere SW |
| 5868W | Solution concentrate for I.V. infusion 80 mg in 8 mL | 1 | .. | .. | 1155.45 | 34.20 ^a | DBL Docetaxel Concentrated Injection HH |
| | | | | | | | ^a Docetaxel Sandoz SZ |
| 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 ^a | Taxotere SW |
| <hr/> | | | | | | | |
| DOCETAXEL | | | | | | | |
| Caution | | | | | | | |
| Pharmaceutical benefits containing docetaxel may have different concentrations. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3918 | | | | | | | |
| Treatment of HER2 positive early breast cancer in combination with trastuzumab. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3892 | | | | | | | |
| Adjuvant treatment of operable breast cancer in combination with cyclophosphamide. | | | | | | | |
| Note | | | | | | | |
| A maximum of four cycles of treatment will be authorised under this restriction. | | | | | | | |
| 5810T | Solution concentrate for I.V. infusion 140 mg in 7 mL | 1 | .. | .. | 2013.30 | 34.20 | Oncotaxel 140 TA |
| <hr/> | | | | | | | |
| DOCETAXEL | | | | | | | |
| Caution | | | | | | | |
| Pharmaceutical benefits containing docetaxel may have different concentrations. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3918 | | | | | | | |
| Treatment of HER2 positive early breast cancer in combination with trastuzumab. | | | | | | | |
| 5957M | Solution concentrate for I.V. infusion 160 mg in 16 mL | 1 | .. | .. | 2310.90 | 34.20 | DBL Docetaxel Concentrated Injection HH |

CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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|---|---|-------------|-------------|---------|--|--|--|
| DOCETAXEL | | | | | | | |
| Caution | | | | | | | |
| Pharmaceutical benefits containing docetaxel may have different concentrations. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3893 | | | | | | | |
| Advanced breast cancer after failure of prior therapy; | | | | | | | |
| 3186 | | | | | | | |
| Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound; | | | | | | | |
| 3890 | | | | | | | |
| Locally advanced or metastatic non-small cell lung cancer. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3884 | | | | | | | |
| Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles. | | | | | | | |
| Note | | | | | | | |
| A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction. | | | | | | | |
| Note | | | | | | | |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and 20 mg in 2 mL, docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) and docetaxel powder for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. | | | | | | | |
| 5591G | Powder for I.V. infusion 20 mg with solvent | 2 | .. | .. | *576.58 | 34.20 | ^a Docetaxel SUN ZF |
| 5855E | Solution concentrate for I.V. infusion 20 mg in 1 mL | 2 | .. | .. | *576.58 | 34.20 | ^a Oncotaxel 20 TA |
| | | | | | | | ^a Taxotere SW |
| 5860K | Solution concentrate for I.V. infusion 20 mg in 2 mL | 2 | .. | .. | *576.58 | 34.20 | ^a DBL Docetaxel Concentrated Injection HH |
| | | | | | | | ^a Docetaxel Ebewe HX |
| | | | | | | | ^a Docetaxel Sandoz SZ |
| 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 | ^a Taxotere SW |

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3893

Advanced breast cancer after failure of prior therapy;

3186

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

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority required (STREAMLINED)

3884

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

Note

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

Note

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

| | | | | | | | |
|-------|--|---|----|----|---------|-------|-------------------------------|
| 5592H | Powder for I.V. infusion 80 mg with solvent | 1 | .. | .. | 1155.45 | 34.20 | ^a Docetaxel SUN ZF |
| 5856F | Solution concentrate for I.V. infusion 80 mg in 4 mL | 1 | .. | .. | 1155.45 | 34.20 | ^a Oncotaxel 80 TA |
| | | | | | | | ^a Taxotere SW |

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 | |
|-------|---|-------------|-------------|---------|--|--|---|----------------|
| 5861L | Solution concentrate for I.V. infusion 80 mg in 8 mL | 1 | .. | .. | 1155.45 | 34.20 ^a | DBL Docetaxel Concentrated Injection Docetaxel Ebewe Docetaxel Sandoz | HH HX SZ |
| 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 ^a | Taxotere | SW |

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3916

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

Note

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

| | | | | | | | | |
|-------|---|---|----|----|---------|--------------------|---|----------------|
| 5593J | Solution concentrate for I.V. infusion 20 mg in 1 mL | 2 | .. | .. | *576.58 | 34.20 ^a | Oncotaxel 20 Taxotere | TA SW |
| 5594K | Solution concentrate for I.V. infusion 20 mg in 2 mL | 2 | .. | .. | *576.58 | 34.20 ^a | DBL Docetaxel Concentrated Injection Docetaxel Ebewe Docetaxel Sandoz | HH HX SZ |
| 5595L | 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 ^a | Taxotere | SW |

DOCETAXEL

Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

Authority required (STREAMLINED)

3888

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

Note

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

Authority required (STREAMLINED)

3916

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

Note

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

| | | | | | | | | |
|-------|---|---|----|----|---------|--------------------|---|----------------|
| 5596M | Solution concentrate for I.V. infusion 80 mg in 4 mL | 1 | .. | .. | 1155.45 | 34.20 ^a | Oncotaxel 80 Taxotere | TA SW |
| 5597N | Solution concentrate for I.V. infusion 80 mg in 8 mL | 1 | .. | .. | 1155.45 | 34.20 ^a | DBL Docetaxel Concentrated Injection Docetaxel Ebewe Docetaxel Sandoz | HH HX SZ |
| 5598P | 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 ^a | Taxotere | SW |

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 |
|--|---|-------------|-------------|---------|--|--|-----------------------------|
| DOCETAXEL | | | | | | | |
| Caution | | | | | | | |
| Pharmaceutical benefits containing docetaxel may have different concentrations. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3892 | | | | | | | |
| Adjuvant treatment of operable breast cancer in combination with cyclophosphamide. | | | | | | | |
| Note | | | | | | | |
| A maximum of four cycles of treatment will be authorised under this restriction. | | | | | | | |
| Note | | | | | | | |
| Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. | | | | | | | |
| 5811W | Solution concentrate for I.V. infusion 20 mg in 1 mL | 2 | .. | .. | *576.58 | 34.20 ^a | Oncotaxel 20 TA |
| | | | | | | ^a | Taxotere SW |
| 5812X | 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 ^a | Taxotere SW |
| <hr/> | | | | | | | |
| DOCETAXEL | | | | | | | |
| Caution | | | | | | | |
| Pharmaceutical benefits containing docetaxel may have different concentrations. | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3892 | | | | | | | |
| Adjuvant treatment of operable breast cancer in combination with cyclophosphamide. | | | | | | | |
| Note | | | | | | | |
| A maximum of four cycles of treatment will be authorised under this restriction. | | | | | | | |
| Note | | | | | | | |
| Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. | | | | | | | |
| 5813Y | Solution concentrate for I.V. infusion 80 mg in 4 mL | 1 | .. | .. | 1155.45 | 34.20 ^a | Oncotaxel 80 TA |
| | | | | | | ^a | Taxotere SW |
| 5814B | 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 ^a | Taxotere SW |
| NAB PACLITAXEL | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3897 | | | | | | | |
| Metastatic breast cancer after failure of prior therapy. | | | | | | | |
| 5847R | Powder for I.V. injection 100 mg (base) | 1 | .. | .. | 401.48 | 34.20 | Abraxane TS |
| PACLITAXEL | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3917 | | | | | | | |
| Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide; | | | | | | | |
| 3893 | | | | | | | |
| Advanced breast cancer after failure of prior therapy; | | | | | | | |
| 3186 | | | | | | | |
| Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound; | | | | | | | |
| 3902 | | | | | | | |
| Primary treatment of ovarian cancer in combination with a platinum compound; | | | | | | | |
| 3890 | | | | | | | |
| Locally advanced or metastatic non-small cell lung cancer; | | | | | | | |
| 3918 | | | | | | | |
| Treatment of HER2 positive early breast cancer in combination with trastuzumab. | | | | | | | |
| 5973J | Solution concentrate for I.V. infusion 30 mg in 5 mL | 5 | .. | .. | 392.48 | 34.20 ^a | Paclitaxel Ebewe SZ |

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 \$ | | | |
| | | | | .. | *392.50 | 34.20 | ^a | Anzatax | HH |
| | | | | | | | ^a | Paclitaxel Actavis | TA |
| | | | | | | | ^a | Paclitaxel Kabi | PK |
| | | | | | | | ^a | Plaxel | WQ |
| | | | | | | | ^a | Taxol | BQ |
| 5974K | Solution concentrate for I.V. infusion 100 mg in 16.7 mL | 2 | .. | .. | *520.74 | 34.20 | ^a | Anzatax | HH |
| | | | | | | | ^a | Paclitaxel Actavis | TA |
| | | | | | | | ^a | Paclitaxel Ebewe | SZ |
| | | | | | | | ^a | Paclitaxel Kabi | PK |
| | | | | | | | ^a | Plaxel | WQ |
| | | | | | | | ^a | Taxol | BQ |
| 5975L | Solution concentrate for I.V. infusion 150 mg in 25 mL | 2 | .. | .. | *759.04 | 34.20 | ^a | Anzatax | HH |
| | | | | | | | ^a | Paclitaxel Actavis | TA |
| | | | | | | | ^a | Paclitaxel Ebewe | SZ |
| | | | | | | | ^a | Plaxel | WQ |
| | | | | | | | ^a | Taxol | BQ |
| 5976M | Solution concentrate for I.V. infusion 300 mg in 50 mL | 1 | .. | .. | 790.88 | 34.20 | ^a | Anzatax | HH |
| | | | | | | | ^a | Paclitaxel Actavis | TA |
| | | | | | | | ^a | Paclitaxel Ebewe | SZ |
| | | | | | | | ^a | Paclitaxel Kabi | PK |
| | | | | | | | ^a | Plaxel | WQ |
| | | | | | | | ^a | Taxol | BQ |

Cytotoxic antibiotics and related substances

Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE

| | | | | | | | | | |
|-------|---|---|----|----|--------|-------|--------------|------------------------|----|
| 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 | ^a | Adriamycin | PF |
| | | | | | | | ^a | Doxorubicin Ebewe | SZ |
| 5925W | Solution for I.V. injection or intravesical administration 10 mg in 5 mL | 4 | .. | .. | *27.52 | 28.61 | ^a | Adriamycin Solution | PF |
| | | | | | | | ^a | Doxorubicin Ebewe | SZ |
| | | | | | | | ^a | 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 | ^a | Adriamycin Solution | PF |
| | | | | | | | ^a | Doxorubicin Ebewe | SZ |
| | | | | | | | ^a | Hospira Pty Limited | HH |

DOXORUBICIN HYDROCHLORIDE, PEGYLATED LIPOSOMAL

Authority required (STREAMLINED)

3905

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

3910

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

3911

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 |

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 | |
|------------------------------------|---|-------------|-------------|---------|--|--|--------------|---|----------------------|
| EPIRUBICIN HYDROCHLORIDE | | | | | | | | | |
| 5884Q | Solution for injection 200 mg in 100 mL | 1 | .. | .. | 666.26 | 34.20 | ^a | DBL Epirubicin Hydrochloride Injection Epirubicin Ebewe Epirubicin Ebewe Hospira Pty Limited | HH SZ HH |
| 5885R | Solution for injection 100 mg in 50 mL | 2 | .. | .. | *676.40 | 34.20 | ^a | Epirubicin Ebewe Hospira Pty Limited | SZ HH |
| 5928B | Solution for injection 10 mg in 5 mL | 4 | .. | .. | *143.64 | 34.20 | ^a | Epirubicin Ebewe 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 | ^a | Epirubicin Ebewe Hospira Pty Limited Pharmorubicin Solution | SZ HH PF |
| IDARUBICIN HYDROCHLORIDE | | | | | | | | | |
| Restricted benefit | | | | | | | | | |
| Acute myelogenous leukaemia. | | | | | | | | | |
| 5941Q | Solution for I.V. injection 5 mg in 5 mL | 3 | .. | .. | *422.52 422.53 | 34.20 | ^a | Idarubicin Ebewe Zavedos Solution | SZ PF |
| 5942R | Solution for I.V. injection 10 mg in 10 mL | 6 | .. | .. | *1633.86 1633.90 | 34.20 | ^a | Idarubicin Ebewe Zavedos Solution | SZ PF |
| MITOZANTRONE HYDROCHLORIDE | | | | | | | | | |
| 5964X | Injection 10 mg (base) in 5 mL | 1 | .. | .. | 65.25 | 34.20 | | Pfizer Australia Pty Ltd | PF |
| 5965Y | Injection 20 mg (base) in 10 mL | 1 | .. | .. | 130.51 | 34.20 | ^a | Hospira Pty Limited Mitozantrone Ebewe Onkotrone Pfizer Australia Pty Ltd | HH SZ BX PF |
| 5966B | Injection 25 mg (base) in 12.5 mL | 1 | .. | .. | 163.05 | 34.20 | ^a | Onkotrone Pfizer Australia Pty Ltd | BX 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 Hospira Pty Limited Pfizer Australia Pty Ltd | SZ HH PF |
| 5907X | Solution for I.V. injection 150 mg in 15 mL | 6 | .. | .. | *356.76 | 34.20 | ^a | Carboplatin Ebewe Hospira Pty Limited Pfizer Australia Pty Ltd | SZ HH PF |
| 5908Y | Solution for I.V. injection 450 mg in 45 mL | 2 | .. | .. | *224.06 | 34.20 | ^a | Carboplatin Ebewe Hospira Pty Limited Pfizer Australia Pty Ltd | SZ HH 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 | 11.80 | ^a | Hospira Pty Limited Pfizer Australia Pty Ltd | HH PF |
| 5911D | I.V. injection 100 mg in 100 mL | 1 | .. | .. | 26.98 | 28.07 | ^a | Cisplatin Ebewe | SZ |

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 \$ | | | |
| | | | | | | | | ^a Hospira Pty Limited | HH |
| | | | | | | | | ^a Pfizer Australia Pty Ltd | PF |
| OXALIPLATIN | | | | | | | | | |
| <u>Authority required (STREAMLINED)</u> | | | | | | | | | |
| 3900 Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with capecitabine; | | | | | | | | | |
| 3901 Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with 5-fluorouracil and folinic acid; | | | | | | | | | |
| 3930 Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with capecitabine; | | | | | | | | | |
| 3939 Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with 5-fluorouracil and folinic acid. | | | | | | | | | |
| <u>Note</u> Oxaliplatin is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer. Oxaliplatin is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer. | | | | | | | | | |
| <u>Note</u> Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 50 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 50 mg are equivalent for the purposes of substitution. | | | | | | | | | |
| 5877H | Solution concentrate for I.V. infusion 50 mg in 10 mL | 1 | 2 | .. | 84.93 | 34.20 | ^a | DBL Oxaliplatin Concentrate | HH |
| | | | | | | | ^a | Eloxatin | SW |
| | | | | | | | ^a | Oxaliplatin Kabi | PK |
| | | | | | | | ^a | Oxaliplatin SUN | ZF |
| 5994L | Powder for I.V. infusion 50 mg | 1 | 2 | .. | 84.93 | 34.20 | ^a | Hospira Pty Limited | HH |
| | | | | | | | ^a | Oxalatin | ZP |
| | | | | | | | ^a | Oxaliplatin Actavis | TA |
| | | | | | | | ^a | Oxaliplatin Alphapharm | AF |
| | | | | | | | ^a | Oxaliplatin Ebewe | SZ |
| | | | | | | | ^a | Oxaliplatin Link | PK |
| | | | | | | | ^a | Xalox | WQ |

OXALIPLATIN

Authority required (STREAMLINED)

3900

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

3901

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

3930

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

3939

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

Note

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

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

Note

Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 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.

| | | | | | | | | | |
|-------|--|---|---|----|--------|-------|--------------|-----------------------------|----|
| 5878J | Solution concentrate for I.V. infusion 100 mg in 20 mL | 1 | 2 | .. | 164.05 | 34.20 | ^a | DBL Oxaliplatin Concentrate | HH |
| | | | | | | | ^a | Eloxatin | SW |
| | | | | | | | ^a | Oxaliplatin Kabi | PK |
| | | | | | | | ^a | Oxaliplatin SUN | ZF |

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 \$ | | | |
| 5995M | Powder for I.V. infusion 100 mg | 1 | 2 | .. | 164.05 | 34.20 | ^a | Hospira Pty Limited | HH |
| | | | | | | | ^a | Oxalatin | ZP |
| | | | | | | | ^a | Oxaliplatin Actavis | TA |
| | | | | | | | ^a | Oxaliplatin | AF |
| | | | | | | | ^a | Alphapharm Oxaliplatin Ebewe | SZ |
| | | | | | | | ^a | Oxaliplatin Link | PK |
| | | | | | | | ^a | Winthrop Oxaliplatin | WA |
| ^a | Xalox | WQ | | | | | | | |

OXALIPLATIN

Authority required (STREAMLINED)

3900

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

3901

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

3930

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

3939

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

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 | .. | 326.99 | 34.20 | ^a | Eloxatin | SW |
| | | | | | | | ^a | Oxaliplatin SUN | ZF |

Monoclonal antibodies

BEVACIZUMAB

Authority required (STREAMLINED)

3894

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

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

Note

Not for use as monotherapy.

Authority required (STREAMLINED)

3896

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

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

Note

Not for use as monotherapy.

Note

Special Pricing Arrangements apply.

| | | | | | | | | |
|-------|--|---|----|----|---------|-------|---------|----|
| 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 (STREAMLINED)

3903

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

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 \$ | |
| 3904 | | | | | | | |
| Continuing PBS-subsidised treatment, as monotherapy or in combination with an irinotecan based therapy, of a patient with K-RAS wild type metastatic colorectal cancer who has previously been issued with an authority prescription for cetuximab and who does not have progressive disease. | | | | | | | |
| Note | | | | | | | |
| Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies. | | | | | | | |
| Note | | | | | | | |
| Special Pricing Arrangements apply. | | | | | | | |
| 5599Q | Solution for I.V. infusion 100 mg in 20 mL | 1 | .. | .. | 341.00 | 34.20 | Erbixux SG |
| 5600R | Solution for I.V. infusion 500 mg in 100 mL | 1 | .. | .. | 1705.00 | 34.20 | Erbixux SG |
| <hr/> | | | | | | | |
| CETUXIMAB | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3919 | | | | | | | |
| Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the TGA-approved Product Information; | | | | | | | |
| 3920 | | | | | | | |
| Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated. | | | | | | | |
| Note | | | | | | | |
| No applications for repeats will be authorised. | | | | | | | |
| 5836E | Solution for I.V. infusion 100 mg in 20 mL | 1 | .. | .. | 341.00 | 34.20 | Erbixux SG |
| 5837F | Solution for I.V. infusion 500 mg in 100 mL | 1 | .. | .. | 1705.00 | 34.20 | Erbixux SG |
| <hr/> | | | | | | | |
| CETUXIMAB | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3921 | | | | | | | |
| Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated. | | | | | | | |
| Note | | | | | | | |
| A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted. | | | | | | | |
| 5838G | Solution for I.V. infusion 100 mg in 20 mL | 1 | 6 | .. | 341.00 | 34.20 | Erbixux SG |
| 5839H | Solution for I.V. infusion 500 mg in 100 mL | 1 | 6 | .. | 1705.00 | 34.20 | Erbixux SG |
| <hr/> | | | | | | | |
| RITUXIMAB | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3908 | | | | | | | |
| Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma; | | | | | | | |
| 3909 | | | | | | | |
| 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 |
| <hr/> | | | | | | | |
| RITUXIMAB | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | |
| 3912 | | | | | | | |
| Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy; | | | | | | | |
| 3915 | | | | | | | |
| Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy. | | | | | | | |
| 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 |

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|---|---|-------------|-------------|---------|--|--|--|
| RITUXIMAB | | | | | | | |
| <u>Authority required (STREAMLINED)</u> | | | | | | | |
| 3932 | | | | | | | |
| CD20 positive, chronic lymphocytic leukaemia, in combination with chemotherapy. | | | | | | | |
| <u>Note</u> | | | | | | | |
| Rituximab is not PBS-subsidised for use as monotherapy. | | | | | | | |
| 5589E | Solution for I.V. infusion 100 mg in 10 mL | 2 | 5 | .. | 905.43 | 34.20 | Mabthera RO |
| 5590F | Solution for I.V. infusion 500 mg in 50 mL | 2 | 5 | .. | *4527.14 | 34.20 | Mabthera RO |
| <i>Other antineoplastic agents</i> | | | | | | | |
| ARSENIC TRIOXIDE | | | | | | | |
| <u>Authority required (STREAMLINED)</u> | | | | | | | |
| 3891 | | | | | | | |
| Induction and consolidation treatment of relapsed acute promyelocytic leukaemia (characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript) in a patient who is arsenic naive at induction. | | | | | | | |
| 5851Y | Injection concentrate 10 mg in 10 mL | 60 | 2 | .. | *24049.68 | 34.20 | Phenasen PL |
| IRINOTECAN HYDROCHLORIDE TRIHYDRATE | | | | | | | |
| <u>Authority required (STREAMLINED)</u> | | | | | | | |
| 3184 | | | | | | | |
| Metastatic colorectal cancer in patients with a WHO performance status of 2 or less. | | | | | | | |
| <u>Note</u> | | | | | | | |
| 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 | ^a Hospira Pty Limited HH ^a Irinotecan Actavis TA 500 ^a Irinotecan Ebewe SZ |
| 5846Q | I.V. injection 300 mg in 15 mL | 1 | 3 | .. | 321.58 | 34.20 | ^a Camptosar PF ^a Irinotecan Ebewe SZ |
| 5958N | I.V. injection 40 mg in 2 mL | 1 | 3 | .. | 42.92 | 34.20 | ^a Camptosar PF ^a Hospira Pty Limited HH ^a Irinotecan Actavis TA ^a Irinotecan AF Alphapharm ^a Irinotecan Ebewe SZ ^a Irinotecan Kabi PK ^a Omegapharm OE Irinotecan ^a Tecan WQ |
| 5959P | I.V. injection 100 mg in 5 mL | 2 | 3 | .. | *214.58 | 34.20 | ^a Camptosar PF ^a Hospira Pty Limited HH ^a Irinotecan Actavis TA ^a Irinotecan AF Alphapharm ^a Irinotecan Ebewe SZ ^a Irinotecan Kabi PK ^a Omegapharm OE Irinotecan ^a Tecan WQ |
| TOPOTECAN HYDROCHLORIDE | | | | | | | |
| <u>Authority required (STREAMLINED)</u> | | | | | | | |
| 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 |

CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

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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 (STREAMLINED)

3180

Hairy cell leukaemia;

3899

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 |
|-------|---|----|---|----|---------|-------|-----------|----|

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 | 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 |

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 | 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 (STREAMLINED)

3180

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 |
|-------|---|---|---|----|---------|-------|------------------|----|

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 | |
|---|---|-------------|-------------|---------|--|--|-----------------------------|------------|
| INTERFERON ALFA-2b | | | | | | | | |
| Caution | | | | | | | | |
| Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. | | | | | | | | |
| Authority required (STREAMLINED) | | | | | | | | |
| 3898 | | | | | | | | |
| Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy; | | | | | | | | |
| 3895 | | | | | | | | |
| 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 ⁸ CFU | 3 | 1 | .. | *405.00 | 34.20 | ImmuCyst | SW |
|-------|---|---|---|----|---------|-------|----------|----|

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 ⁸ CFU | 3 | 1 | .. | 491.83 | 34.20 | OncoTICE | MK |
|-------|--|---|---|----|--------|-------|----------|----|

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 |
|------|---|-------------|-------------|---------|--|--|-----------------------------|
|------|---|-------------|-------------|---------|--|--|-----------------------------|

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 | ^a Calcium Folate Ebewe | SZ |
| | | | | | | | ^a Leucovorin Calcium (Hospira Pty Limited) | HH |
| 5886T | Injection equivalent to 100 mg folinic acid in 10 mL | 10 | 1 | .. | *217.90 | 34.20 | ^a Calcium Folate Ebewe | SZ |
| | | | | .. | 217.97 | 34.20 | ^a Leucovorin Calcium (Pfizer Australia Pty Ltd) | PF |
| 5890B | Injection equivalent to 50 mg folinic acid in 5 mL | 5 | 5 | .. | *118.05 | 34.20 | ^a Leucovorin Calcium (Hospira Pty Limited) | HH |
| | | | | .. | 118.10 | 34.20 | ^a Calcium Folate Ebewe | SZ |
| | | | | .. | *119.17 | 34.20 | ^a 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 |
|-------|---|----|----|----|-------|-------|--|----|

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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