



**Australian Government**  

---

**Department of Health and Ageing**

## **SCHEDULE OF PHARMACEUTICAL BENEFITS**

### **EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS SUPPLEMENT**

This schedule is also available on the internet at

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

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the National Health Act 1953. However, at the time of distribution the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislative Instruments website at <http://www.frl.gov.au>.

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## SUMMARY OF CHANGES

### Additions

#### Addition – Brand

|       |   |
|-------|---|
| 7233Q | <i>AS-Fludarabine, YA – <b>Fludarabine</b>, fludarabine phosphate 50 mg/2 mL injection, 1 x 2 mL vial</i> |
| 4393F | <i>AS-Fludarabine, YA – <b>Fludarabine</b>, fludarabine phosphate 50 mg/2 mL injection, 1 x 2 mL vial</i> |
| 7246J | <i>AS-Gemcitabine, YA – <b>Gemcitabine</b>, gemcitabine 200 mg injection, 1 x 200 mg vial</i>             |
| 4439P | <i>AS-Gemcitabine, YA – <b>Gemcitabine</b>, gemcitabine 200 mg injection, 1 x 200 mg vial</i>             |
| 7246J | <i>AS-Gemcitabine, YA – <b>Gemcitabine</b>, gemcitabine 2 g injection, 1 x 2 g vial</i>                   |
| 4439P | <i>AS-Gemcitabine, YA – <b>Gemcitabine</b>, gemcitabine 2 g injection, 1 x 2 g vial</i>                   |
| 7246J | <i>AS-Gemcitabine, YA – <b>Gemcitabine</b>, gemcitabine 1 g injection, 1 x 1 g vial</i>                   |
| 4439P | <i>AS-Gemcitabine, YA – <b>Gemcitabine</b>, gemcitabine 1 g injection, 1 x 1 g vial</i>                   |
| 7253R | <i>AS-Oxaliplatin, YA – <b>Oxaliplatin</b>, oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial</i>        |
| 4542C | <i>AS-Oxaliplatin, YA – <b>Oxaliplatin</b>, oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial</i>        |
| 7253R | <i>AS-Oxaliplatin, YA – <b>Oxaliplatin</b>, oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial</i>         |
| 4542C | <i>AS-Oxaliplatin, YA – <b>Oxaliplatin</b>, oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial</i>         |
| 7253R | <i>AS-Oxaliplatin, YA – <b>Oxaliplatin</b>, oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial</i>        |
| 4542C | <i>AS-Oxaliplatin, YA – <b>Oxaliplatin</b>, oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial</i>        |
| 7254T | <i>GN-Paclitaxel, YA – <b>Paclitaxel</b>, paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial</i>              |
| 4567J | <i>GN-Paclitaxel, YA – <b>Paclitaxel</b>, paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial</i>              |
| 7254T | <i>GN-Paclitaxel, YA – <b>Paclitaxel</b>, paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial</i>       |
| 4567J | <i>GN-Paclitaxel, YA – <b>Paclitaxel</b>, paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial</i>       |
| 7254T | <i>GN-Paclitaxel, YA – <b>Paclitaxel</b>, paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial</i>           |
| 4567J | <i>GN-Paclitaxel, YA – <b>Paclitaxel</b>, paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial</i>           |
| 7260D | <i>Topotecan Agila, YA – <b>Topotecan</b>, topotecan 4 mg injection, 1 x 4 mg vial</i>                    |
| 4617B | <i>Topotecan Agila, YA – <b>Topotecan</b>, topotecan 4 mg injection, 1 x 4 mg vial</i>                    |
| 7263G | <i>AS-Vinorelbine, YA – <b>Vinorelbine</b>, vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial</i>           |
| 4620E | <i>AS-Vinorelbine, YA – <b>Vinorelbine</b>, vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial</i>           |
| 7263G | <i>AS-Vinorelbine, YA – <b>Vinorelbine</b>, vinorelbine 10 mg/mL injection, 1 x 1 mL vial</i>             |
| 4620E | <i>AS-Vinorelbine, YA – <b>Vinorelbine</b>, vinorelbine 10 mg/mL injection, 1 x 1 mL vial</i>             |

# EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS

## Explanatory Notes

In addition to the drugs and medicinal preparations listed in the Schedule of Pharmaceutical Benefits, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements. These alternative arrangements are provided for under section 100 of the *National Health Act 1953*.

## Section 100 cancer chemotherapy drugs

New prescribing and dispensing arrangements for certain chemotherapy drugs subsidised by the Pharmaceutical Benefits Scheme (PBS) came into effect on 1 December 2011 under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs initiative (Revised Arrangements).

Chemotherapy drugs used for the treatment of cancer and administered through infusion or injection are covered by these Revised Arrangements. The Revised Arrangements operate under a section 100 program which includes certain intravenous chemotherapy drugs, as listed in this Schedule, which were previously supplied through:

- the General Pharmaceutical Benefits Schedule (section 2)
- the Special Authority Program (trastuzumab - Herceptin<sup>®</sup>), and
- the Chemotherapy Pharmaceutical Access Program (CPAP).

This Schedule is split into two parts:

### 1) Chemotherapy items for private hospital/private clinic use

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

### 2a) Chemotherapy items for public hospital use

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

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

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

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

## Prescribing and Supplying - Information for PBS Prescribers and Pharmacists

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

Chemotherapy drugs are listed based on the relevant unit of measure. Prescribers of these drugs must write dose specific prescriptions, which specify the amount of active ingredient/s required for a single infusion or injection using milligrams or other relevant units of measure.

- Prescribing will exclude reference to forms and strengths
- Loading and maintenance doses will need to be prescribed separately
- Prescriptions will no longer take the form of an order for a certain number of items, but will instead order an amount of a drug or drugs at the generic (drug) level for a specific infusion/injection
- Prescribers retain the right to prescribe by brand.

This Schedule has been updated to include:

- one item code per drug (in most circumstances) under which brands, forms and strengths are listed
- maximum amount (which replaces maximum quantity) refers to the upper limit in milligrams or other relevant unit of measure

Dispensing software has been upgraded to include an algorithm which will calculate the most cost-efficient combination of vial sizes that make up the required patient dose (one prescription) and calculate the level of remuneration paid.

The algorithm does not determine how the infusion is prepared, however remuneration will be made based on the most cost-efficient combination of vial sizes. Pharmacists will still be able to dispense any subsidised brand or combination of brands.

A dose variation will be allowed by up to 10 percent from the original amount prescribed on the recommendation of the prescriber without requirement for a new prescription.

Same day prescribing will be allowed. Regulations 24 (immediate supply necessary) and 25 (hardship provisions) will not apply for items under this initiative.

To recognise the specialist nature of dispensing chemotherapy drugs the Government has determined new remuneration arrangements. The fee structure for community pharmacies, public hospitals and private hospitals is provided below.

For more information on prescribing and supplying chemotherapy medicines subject to the Revised Arrangements, refer to the PBS website at [www.pbs.gov.au](http://www.pbs.gov.au).

## Authorisation requirements

Authorisation requirements have not been varied by the Revised Arrangements. Items that require an Authority continue to require an Authority from Medicare.

Prior approval is not needed for Authority Required (STREAMLINED) items (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code. Under the Revised Arrangements more items are available as Authority Required (STREAMLINED).

For more information on authorisation requirements, refer to the Explanatory Notes of the Schedule of Pharmaceutical Benefits at [www.pbs.gov.au](http://www.pbs.gov.au) or the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au).

## Brand equivalence

An 'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

For other brands of an item, i.e., those not indicated as above, it is unknown whether or not they are equivalent. There may be several reasons for this, such as bioequivalence data not being considered necessary when the products were approved for marketing, or that advice or data have not been forthcoming from sponsors. This does not necessarily suggest a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.

## Remuneration arrangements

Fees payable per item claimed:

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

- Ready Prepared Dispensing Fee (\$6.52)
- Preparation fee (\$40.64)
- Distribution fee (\$24.38)
- Diluent fee (\$4.83)

### Section 94 Approved Public Hospital Authority

- Preparation fee (\$40.64)

### Section 94 Approved Private Hospital Authority

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

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

### Special Pharmaceutical Benefits for Private Hospital/Private Clinic use

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

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

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ANTINEOPLASTIC AGENTS

#### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

##### *Other cytotoxic antibiotics*

##### BLEOMYCIN SULFATE

##### Restricted benefit

Germ cell neoplasms

##### Restricted benefit

Lymphoma

|       |           |          |    |         |         |         |       |   |          |
|-------|-----------|----------|----|---------|---------|---------|-------|---|----------|
| 7244G | Injection | 30000 iu | 11 | \$67.94 | *151.95 | *219.89 | 36.10 | Bleo 15K (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial)<br>Hospira Pty Limited (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial) | WQ<br>HH |
|-------|-----------|----------|----|---------|---------|---------|-------|---|----------|

## Chemotherapy Items for Private Hospital/Private Clinic use

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

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ALKYLATING AGENTS

#### *Nitrogen mustard analogues*

##### CYCLOPHOSPHAMIDE

|       |           |         |    |    |         |       |  |    |
|-------|-----------|---------|----|----|---------|-------|--|----|
| 7226H | Injection | 2800 mg | 17 | .. | *146.36 | 36.10 | Endoxan (cyclophosphamide 1 g injection, 1 x 1 g vial)       | BX |
|       |           |         |    |    |         |       | Endoxan (cyclophosphamide 2 g injection, 1 x 2 g vial)       | BX |
|       |           |         |    |    |         |       | Endoxan (cyclophosphamide 500 mg injection, 1 x 500 mg vial) | BX |

##### IFOSFAMIDE

##### Restricted benefit

Relapsed or refractory germ cell tumours following first-line chemotherapy

##### Restricted benefit

Relapsed or refractory sarcomas following first-line chemotherapy

|       |           |         |    |    |         |       |  |    |
|-------|-----------|---------|----|----|---------|-------|--|----|
| 7248L | Injection | 4000 mg | 19 | .. | *330.97 | 36.10 | Holoxan (ifosfamide 1 g injection, 1 x 1 g vial) | BX |
|       |           |         |    |    |         |       | Holoxan (ifosfamide 2 g injection, 1 x 2 g vial) | BX |

#### *Nitrosoureas*

##### FOTEMUSTINE

##### Authority required (STREAMLINED)

**3181**

Metastatic malignant melanoma

|       |           |        |   |    |          |       |  |    |
|-------|-----------|--------|---|----|----------|-------|--|----|
| 7245H | Injection | 220 mg | 8 | .. | *2315.03 | 36.10 | Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&) inert substance diluent [1 x 4 mL ampoule], 1 pack) | SE |
|-------|-----------|--------|---|----|----------|-------|--|----|

### ANTIMETABOLITES

#### *Folic acid analogues*

##### METHOTREXATE

|       |           |        |   |    |        |       |  |    |
|-------|-----------|--------|---|----|--------|-------|--|----|
| 7250N | Injection | 250 mg | 5 | .. | *97.97 | 36.10 | Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)       | HH |
|       |           |        |   |    |        |       | Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)       | HH |
|       |           |        |   |    |        |       | Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)      | HH |
|       |           |        |   |    |        |       | Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)    | HH |
|       |           |        |   |    |        |       | Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)                         | WQ |
|       |           |        |   |    |        |       | Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)                | WQ |
|       |           |        |   |    |        |       | Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)        | SZ |
|       |           |        |   |    |        |       | Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)        | SZ |
|       |           |        |   |    |        |       | Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) | PF |

##### METHOTREXATE

##### Restricted benefit

Patients receiving treatment with a high dose regimen.

|       |           |          |    |    |          |       |   |    |
|-------|-----------|----------|----|----|----------|-------|---|----|
| 7251P | Injection | 20000 mg | .. | .. | *1639.97 | 36.10 | Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)  | HH |
|       |           |          |    |    |          |       | Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)  | HH |
|       |           |          |    |    |          |       | Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) | HH |

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction, Manner of Administration | Max. Amount | No. of Rpts | Premium \$ | Dispensed Price for Max. Amount \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer  |    |
|---|---|-------------|-------------|------------|------------------------------------|--|--|----|
|   |   |             |             |            |                                    |  | Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)    | HH |
|   |   |             |             |            |                                    |  | Methacord (METHOTREXATE Injection 50 mg in 2 mL, 1)                          | WQ |
|   |   |             |             |            |                                    |  | Methacord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)                 | WQ |
|   |   |             |             |            |                                    |  | Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)        | SZ |
|   |   |             |             |            |                                    |  | Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)        | SZ |
|   |   |             |             |            |                                    |  | Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) | PF |
| <b>PEMETREXED</b>   |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required</u></b>  |   |             |             |            |                                    |  |  |    |
| 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  |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required</u></b>  |   |             |             |            |                                    |  |  |    |
| Mesothelioma in combination with cisplatin.   |   |             |             |            |                                    |  |  |    |
| Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval  |   |             |             |            |                                    |  |  |    |
| 7255W   | Injection                                   | 1100 mg     | 5           | ..         | *3561.08                           | 36.10                                      | Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial)                        | LY |
|   |   |             |             |            |                                    |  | Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial)                        | LY |
| <b>RALTITREXED</b>  |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |             |             |            |                                    |  |  |    |
| <b>3185</b>   |   |             |             |            |                                    |  |  |    |
| For use as a single agent in the treatment of advanced colorectal cancer  |   |             |             |            |                                    |  |  |    |
| 7256X   | Injection                                   | 7 mg        | 8           | ..         | *1130.25                           | 36.10                                      | Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial)                          | HH |
| <b>Purine analogues</b>   |   |             |             |            |                                    |  |  |    |
| <b>CLADRIBINE</b>   |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |             |             |            |                                    |  |  |    |
| <b>3180</b>   |   |             |             |            |                                    |  |  |    |
| Hairy cell leukaemia  |   |             |             |            |                                    |  |  |    |
| 7225G   | Injection                                   | 17 mg       | 6           | ..         | *1408.53                           | 36.10                                      | Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial)                 | JC |
|   |   |             |             |            |                                    |  | Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial)                       | OA |
| <b>FLUDARABINE</b>  |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |             |             |            |                                    |  |  |    |
| <b>3887</b>   |   |             |             |            |                                    |  |  |    |
| 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  |   |             |             |            |                                    |  |  |    |
| <b>Note</b>   |   |             |             |            |                                    |  |  |    |
| Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical benefits that have the form fludarabine phosphate solution for I.V. injection 50 mg are equivalent for the purposes of substitution.   |   |             |             |            |                                    |  |  |    |
| 7233Q   | Injection                                   | 55 mg       | 29          | ..         | *646.79                            | 36.10                                      | AS-Fludarabine (fludarabine phosphate 50 mg/2 mL injection, 1 x 2 mL vial)   | YA |
|   |   |             |             |            |                                    |  | Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)               | WQ |
|   |   |             |             |            |                                    |  | Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)             | GZ |

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code   | Name, Restriction, Manner of Administration | Max. Amount | No. of Rpts | Premium \$ | Dispensed Price for Max. Amount \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer  |    |
|--|---|-------------|-------------|------------|------------------------------------|--|--|----|
|  |   |             |             |            |                                    |  | Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)        | TA |
|  |   |             |             |            |                                    |  | Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)     | SZ |
| <b>Pyrimidine analogues</b>  |   |             |             |            |                                    |  |  |    |
| <b>CYTARABINE</b>  |   |             |             |            |                                    |  |  |    |
| 7227J  | Injection                                   | 7000 mg     | 15          | ..         | *810.67                            | 36.10                                      | Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)        | PF |
| <b>FLUOROURACIL</b>  |   |             |             |            |                                    |  |  |    |
| <b>Restricted benefit</b>  |   |             |             |            |                                    |  |  |    |
| For patients requiring administration of fluorouracil by intravenous infusion.   |   |             |             |            |                                    |  |  |    |
| 7234R  | Injection                                   | 5500 mg     | 11          | ..         | *118.53                            | 36.10                                      | DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)  | HH |
|  |   |             |             |            |                                    |  | DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) | HH |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)              | SZ |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)            | SZ |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)            | SZ |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)          | SZ |
|  |   |             |             |            |                                    |  | Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)         | HH |
| <b>FLUOROURACIL</b>  |   |             |             |            |                                    |  |  |    |
| <b>Restricted benefit</b>  |   |             |             |            |                                    |  |  |    |
| For patients requiring administration of fluorouracil by intravenous injection.  |   |             |             |            |                                    |  |  |    |
| 7239B  | Injection                                   | 1000 mg     | 23          | ..         | *84.35                             | 36.10                                      | DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)  | HH |
|  |   |             |             |            |                                    |  | DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) | HH |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)              | SZ |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)            | SZ |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)            | SZ |
|  |   |             |             |            |                                    |  | Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)          | SZ |
|  |   |             |             |            |                                    |  | Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)         | HH |
| <b>GEMCITABINE</b>   |   |             |             |            |                                    |  |  |    |
| <b>Caution</b>   |   |             |             |            |                                    |  |  |    |
| Pharmaceutical benefits containing gemcitabine may have different concentrations.  |   |             |             |            |                                    |  |  |    |
| <b>Note</b>  |   |             |             |            |                                    |  |  |    |
| Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL, gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL and gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution.      |   |             |             |            |                                    |  |  |    |
| <b>Note</b>  |   |             |             |            |                                    |  |  |    |
| Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL and gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.   |   |             |             |            |                                    |  |  |    |
| <b>Note</b>  |   |             |             |            |                                    |  |  |    |
| Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL, gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL and gemcitabine solution for injection 200 mg (as hydrochloride) in 5.3 mL are equivalent for the purposes of substitution. |   |             |             |            |                                    |  |  |    |
| 7246J  | Injection                                   | 3000 mg     | 17          | ..         | *274.08                            | 36.10                                      | AS-Gemcitabine (gemcitabine 1 g injection, 1 x 1 g vial)                           | YA |
|  |   |             |             |            |                                    |  | AS-Gemcitabine (gemcitabine 2 g injection, 1 x 2 g vial)                           | YA |

## Chemotherapy Items for Private Hospital/Private Clinic use

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

### PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

#### *Vinca alkaloids and analogues*

|                    |           |       |    |    |         |       |  |    |
|--------------------|-----------|-------|----|----|---------|-------|--|----|
| <b>VINBLASTINE</b> |           |       |    |    |         |       |  |    |
| 7261E              | Injection | 20 mg | 17 | .. | *137.13 | 36.10 | Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials) | HH |
| <b>VINCRIStINE</b> |           |       |    |    |         |       |  |    |
| 7262F              | Injection | 2 mg  | 7  | .. | *104.73 | 36.10 | Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)      | HH |

#### **VINORELBINE**

**Authority required (STREAMLINED)**

**3890**

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction, Manner of Administration   | Max. Amount | No. of Rpts | Premium \$ | Dispensed Price for Max. Amount \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer   |    |
|-------|---|-------------|-------------|------------|------------------------------------|--|---|----|
|       | Locally advanced or metastatic non-small cell lung cancer                             |             |             |            |                                    |  |   |    |
|       | <b>Authority required (STREAMLINED)</b>   |             |             |            |                                    |  |   |    |
|       | <b>3907</b>   |             |             |            |                                    |  |   |    |
|       | Advanced breast cancer after failure of prior therapy which includes an anthracycline |             |             |            |                                    |  |   |    |
| 7263G | Injection   | 70 mg       | 7           | ..         | *227.99                            | 36.10                                      | AS-Vinorelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)        | YA |
|       |   |             |             |            |                                    |  | AS-Vinorelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)      | YA |
|       |   |             |             |            |                                    |  | Hospira Pty Limited (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)   | HH |
|       |   |             |             |            |                                    |  | Hospira Pty Limited (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) | HH |
|       |   |             |             |            |                                    |  | Navelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)             | FB |
|       |   |             |             |            |                                    |  | Navelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)           | FB |
|       |   |             |             |            |                                    |  | Vinorelbine Ebewe (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)     | SZ |
|       |   |             |             |            |                                    |  | Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)   | SZ |
|       |   |             |             |            |                                    |  | Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)    | PK |

### Podophyllotoxin derivatives

|       |                  |        |    |    |         |       |   |    |
|-------|------------------|--------|----|----|---------|-------|---|----|
|       | <b>ETOPOSIDE</b> |        |    |    |         |       |   |    |
| 7237X | Injection        | 440 mg | 14 | .. | *222.47 | 36.10 | Etopophos (etoposide 1 g injection, 1 x 1 g vial)                 | BQ |
|       |                  |        |    |    |         |       | Etopophos (etoposide 100 mg injection, 1 x 100 mg vial)           | BQ |
|       |                  |        |    |    |         |       | Etoposide Ebewe (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) | SZ |

### Taxanes

#### CABAZITAXEL

##### Authority required

Castration resistant metastatic carcinoma of the prostate

##### The Clinical criteria is:

The treatment must be in combination with prednisone or prednisolone,

##### AND the Clinical criteria is:

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

##### AND the Clinical criteria is:

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

##### Note

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

##### Note

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

##### Note

Special Pricing Arrangements apply.

|       |           |       |   |    |          |       |  |    |
|-------|-----------|-------|---|----|----------|-------|--|----|
| 7236W | Injection | 55 mg | 5 | .. | *5961.11 | 36.10 | Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1) | SW |
|-------|-----------|-------|---|----|----------|-------|--|----|

#### DOCETAXEL

##### Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

##### Authority required (STREAMLINED)

##### 3916

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

##### Note

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

##### Note

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V.

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|--|---|-------------|-------------|------------|------------------------------------|--|--|----|
| infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. |   |             |             |            |                                    |  |  |    |
| 7281F  | Injection                                   | 250 mg      | 5           | ..         | *1002.81                           | 36.10                                      | DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)                      | HH |
|  |   |             |             |            |                                    |  | DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                         | HH |
|  |   |             |             |            |                                    |  | DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                         | HH |
|  |   |             |             |            |                                    |  | Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)  | HX |
|  |   |             |             |            |                                    |  | Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)  | HX |
|  |   |             |             |            |                                    |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)   | SZ |
|  |   |             |             |            |                                    |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)   | SZ |
|  |   |             |             |            |                                    |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)   | TA |
|  |   |             |             |            |                                    |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | TA |
|  |   |             |             |            |                                    |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | TA |
|  |   |             |             |            |                                    |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | SW |
|  |   |             |             |            |                                    |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (& inert substance diluent [1 x 6 mL vial], 1 pack) | SW |
|  |   |             |             |            |                                    |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | SW |

### DOCETAXEL

#### Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

#### Authority required (STREAMLINED)

3956

Treatment of HER2 positive breast cancer in combination with trastuzumab

#### Note

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

#### Note

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

|       |           |        |   |    |          |       |   |    |
|-------|-----------|--------|---|----|----------|-------|---|----|
| 7282G | Injection | 250 mg | 5 | .. | *1002.81 | 36.10 | DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial) | HH |
|       |           |        |   |    |          |       | DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)    | HH |
|       |           |        |   |    |          |       | DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)    | HH |
|       |           |        |   |    |          |       | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                        | SZ |
|       |           |        |   |    |          |       | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                        | SZ |
|       |           |        |   |    |          |       | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)                          | TA |
|       |           |        |   |    |          |       | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)                              | TA |
|       |           |        |   |    |          |       | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)                            | TA |
|       |           |        |   |    |          |       | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)                                  | SW |
|       |           |        |   |    |          |       | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2   | SW |

## Chemotherapy Items for Private Hospital/Private Clinic use

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|--|---|----------------|-------------------|---------------|--|--|---|
|  |   |                |                   |               |  |  | mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)<br>Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) SW  |
| <hr/>  |   |                |                   |               |  |  |   |
| <b>DOCETAXEL</b>   |   |                |                   |               |  |  |   |
| <b>Caution</b>   |   |                |                   |               |  |  |   |
| Pharmaceutical benefits containing docetaxel may have different concentrations.  |   |                |                   |               |  |  |   |
| <b>Authority required (STREAMLINED)</b>  |   |                |                   |               |  |  |   |
| <b>3888</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>Note</b>  |   |                |                   |               |  |  |   |
| The carcinoma can be considered inoperable for technical or organ preservation reasons.  |   |                |                   |               |  |  |   |
| <b>Note</b>  |   |                |                   |               |  |  |   |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. |   |                |                   |               |  |  |   |
| <b>Note</b>  |   |                |                   |               |  |  |   |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. |   |                |                   |               |  |  |   |
| 7283H  | Injection   | 250 mg         | 5                 | ..            | *1002.81                                       | 36.10  | DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial) HH<br>DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) HH<br>DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) HH<br>Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) HX<br>Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) HX<br>Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) SZ<br>Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) SZ<br>Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial) TA<br>Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial) TA<br>Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) TA<br>Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial) SW<br>Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack) SW<br>Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) SW |

**DOCETAXEL****Caution**

Pharmaceutical benefits containing docetaxel may have different concentrations.

**Authority required (STREAMLINED)****3892**

Adjuvant treatment of operable breast cancer in combination with cyclophosphamide

**Note**

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

**Note**

A maximum of four cycles of treatment will be authorised under this restriction.

## Chemotherapy Items for Private Hospital/Private Clinic use

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|--|---|-------------|-------------|------------|------------------------------------|--|---|----|
| <b>Note</b>  |   |             |             |            |                                    |  |   |    |
| Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and pharmaceutical benefits that have the form docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. |   |             |             |            |                                    |  |   |    |
| 7284J  | Injection                                   | 250 mg      | 5           | ..         | *1002.81                           | 36.10                                      | DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)                       | HH |
|  |   |             |             |            |                                    |  | DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                          | HH |
|  |   |             |             |            |                                    |  | DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                          | HH |
|  |   |             |             |            |                                    |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)  | SZ |
|  |   |             |             |            |                                    |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)  | SZ |
|  |   |             |             |            |                                    |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)  | TA |
|  |   |             |             |            |                                    |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)  | TA |
|  |   |             |             |            |                                    |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)  | TA |
|  |   |             |             |            |                                    |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)  | SW |
|  |   |             |             |            |                                    |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (& inert substance diluent [1 x 6 mL vial]), 1 pack) | SW |
|  |   |             |             |            |                                    |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)  | SW |

### DOCETAXEL

#### Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

#### Authority required (STREAMLINED)

4078

Locally advanced or metastatic non-small cell lung cancer

#### Authority required (STREAMLINED)

4140

Advanced metastatic ovarian cancer

#### The Clinical criteria is:

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

#### Authority required (STREAMLINED)

4155

Androgen independent (castration resistant) metastatic carcinoma of the prostate

#### The Clinical criteria is:

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

#### AND the Clinical criteria is:

The treatment must be used as first-line chemotherapy,

#### AND the Clinical criteria is:

The treatment must be administered in three weekly cycles,

#### AND the Clinical criteria is:

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

#### Note

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

#### Note

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

#### Authority required (STREAMLINED)

4160

Metastatic breast cancer

#### Note

## Chemotherapy Items for Private Hospital/Private Clinic use

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|--|---|----------------|-------------------|---------------|--|--|--|----|
| <p>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.</p> <p>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.</p>  |   |                |                   |               |  |  |  |    |
| 7285K  | Injection   | 250 mg         | 5                 | ..            | *1002.81                                       | 36.10  | DBL Docetaxel Concentrated Injection<br>(docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)                     | HH |
|  |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                        | HH |
|  |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                        | HH |
|  |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)  | HX |
|  |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)  | HX |
|  |   |                |                   |               |  |  | Docetaxel SUN (docetaxel 20 mg injection [1 x 20 mg vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack) | ZF |
|  |   |                |                   |               |  |  | Docetaxel SUN (docetaxel 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 x 4 mL vial], 1 pack) | ZF |
|  |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)   | SZ |
|  |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)   | SZ |
|  |   |                |                   |               |  |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)   | TA |
|  |   |                |                   |               |  |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | TA |
|  |   |                |                   |               |  |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | TA |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | SW |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)  | SW |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | SW |
| <p><b>PACLITAXEL</b><br/> <b><u>Authority required (STREAMLINED)</u></b><br/> <b>3890</b><br/>           Locally advanced or metastatic non-small cell lung cancer</p> <p><b><u>Authority required (STREAMLINED)</u></b><br/> <b>3902</b><br/>           Primary treatment of ovarian cancer in combination with a platinum compound</p> <p><b><u>Authority required (STREAMLINED)</u></b><br/> <b>3186</b><br/>           Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound</p> <p><b><u>Authority required (STREAMLINED)</u></b><br/> <b>3917</b><br/>           Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide</p> <p><b><u>Authority required (STREAMLINED)</u></b><br/> <b>3956</b><br/>           Treatment of HER2 positive breast cancer in combination with trastuzumab</p> <p><b><u>Authority required (STREAMLINED)</u></b><br/> <b>3955</b><br/>           Metastatic breast cancer</p> |   |                |                   |               |  |  |  |    |
| 7254T  | Injection   | 450 mg         | 3                 | ..            | *1260.47                                       | 36.10  | Anzatax (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)  | HH |
|  |   |                |                   |               |  |  | Anzatax (paclitaxel 150 mg/25 mL injection, 1 x  | HH |

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|------|---|----------------|-------------------|---------------|--|--|---|
|      |   |                |                   |               |  |  | 25 mL vial)   |
|      |   |                |                   |               |  |  | Anzatax (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) HH                   |
|      |   |                |                   |               |  |  | Anzatax (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) HH                |
|      |   |                |                   |               |  |  | GN-Paclitaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) YA      |
|      |   |                |                   |               |  |  | GN-Paclitaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) YA             |
|      |   |                |                   |               |  |  | GN-Paclitaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) YA          |
|      |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) TA |
|      |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) TA     |
|      |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) TA        |
|      |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) TA     |
|      |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) SZ   |
|      |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) SZ       |
|      |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials) SZ         |
|      |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) SZ       |
|      |   |                |                   |               |  |  | Paclitaxel Kabi (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) PK    |
|      |   |                |                   |               |  |  | Paclitaxel Kabi (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) PK           |
|      |   |                |                   |               |  |  | Paclitaxel Kabi (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) PK        |
|      |   |                |                   |               |  |  | Paclitaxel Pfizer (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) PF  |
|      |   |                |                   |               |  |  | Paclitaxel Pfizer (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) PF         |
|      |   |                |                   |               |  |  | Paclitaxel Pfizer (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) PF      |
|      |   |                |                   |               |  |  | Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) WQ             |
|      |   |                |                   |               |  |  | Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial) WQ                 |
|      |   |                |                   |               |  |  | Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) WQ                    |
|      |   |                |                   |               |  |  | Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) WQ                 |
|      |   |                |                   |               |  |  | Taxol (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) BQ              |
|      |   |                |                   |               |  |  | Taxol (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) BQ                     |
|      |   |                |                   |               |  |  | Taxol (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) BQ                  |

### PACLITAXEL NANOPARTICLE ALBUMIN BOUND

#### Authority required (STREAMLINED)

3955

Metastatic breast cancer

#### Authority required (STREAMLINED)

3956

Treatment of HER2 positive breast cancer in combination with trastuzumab

|       |           |        |   |    |          |       |  |    |
|-------|-----------|--------|---|----|----------|-------|--|----|
| 7270P | Injection | 580 mg | 5 | .. | *2555.27 | 36.10 | Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial) | TS |
|-------|-----------|--------|---|----|----------|-------|--|----|

## CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

### *Anthracyclines and related substances*

#### DOXORUBICIN

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction, Manner of Administration | Max. Amount | No. of Rpts | Premium \$ | Dispensed Price for Max. Amount \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer  |    |
|---|---|-------------|-------------|------------|------------------------------------|--|--|----|
| 7229L   | Injection/intravenous                       | 135 mg      | 11          | ..         | *139.52                            | 36.10                                      | Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                         | WQ |
|   |   |             |             |            |                                    |  | Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                    | WQ |
|   |   |             |             |            |                                    |  | Adriamycin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                            | PF |
|   |   |             |             |            |                                    |  | Adriamycin Solution (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                      | PF |
|   |   |             |             |            |                                    |  | Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                          | SZ |
|   |   |             |             |            |                                    |  | Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)                       | SZ |
|   |   |             |             |            |                                    |  | Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                     | SZ |
|   |   |             |             |            |                                    |  | Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                        | SZ |
|   |   |             |             |            |                                    |  | Hospira Pty Limited (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                        | HH |
|   |   |             |             |            |                                    |  | Hospira Pty Limited (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                      | HH |
| <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      |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required</u></b>  |   |             |             |            |                                    |  |  |    |
| Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane |   |             |             |            |                                    |  |  |    |
| <b><u>Authority required</u></b>  |   |             |             |            |                                    |  |  |    |
| Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated      |   |             |             |            |                                    |  |  |    |
| 7228K   | Injection                                   | 100 mg      | 5           | ..         | *3261.32                           | 36.10                                      | Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)               | JC |
| 7230M   | Injection                                   | 100 mg      | 5           | ..         | *3112.97                           | 36.10                                      | Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)               | JC |
|   |   |             |             |            |                                    |  | Caelyx (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)               | JC |
|   |   |             |             |            |                                    |  | Lipodox (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)              | ZF |
|   |   |             |             |            |                                    |  | Lipodox 50 (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)           | ZF |
| <b>EPIRUBICIN</b>   |   |             |             |            |                                    |  |  |    |
| 7231N   | Injection/intravenous                       | 220 mg      | 5           | ..         | *248.34                            | 36.10                                      | DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) | HH |
|   |   |             |             |            |                                    |  | Epiccord (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                                    | WQ |
|   |   |             |             |            |                                    |  | Epiccord (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)                                  | WQ |
|   |   |             |             |            |                                    |  | Epiccord (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                               | WQ |
|   |   |             |             |            |                                    |  | Epiccord (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                                  | WQ |
|   |   |             |             |            |                                    |  | Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                       | TA |
|   |   |             |             |            |                                    |  | Epirubicin Actavis 100 (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)                   | TA |
|   |   |             |             |            |                                    |  | Epirubicin Actavis 20 (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)                     | TA |
|   |   |             |             |            |                                    |  | Epirubicin Actavis 200 (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                 | TA |
|   |   |             |             |            |                                    |  | Epirubicin Actavis 50 (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                     | TA |
|   |   |             |             |            |                                    |  | Epirubicin Ebewe (epirubicin hydrochloride 10  | SZ |

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|------------------------------------|---|----------------|-------------------|---------------|--|--|---|----|
|                                    |   |                |                   |               |  |  | mg/5 mL injection, 1 x 5 mL vial)   |    |
|                                    |   |                |                   |               |  |  | Epirubicin Ebewe (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)        | SZ |
|                                    |   |                |                   |               |  |  | Epirubicin Ebewe (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)      | SZ |
|                                    |   |                |                   |               |  |  | Epirubicin Ebewe (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)         | SZ |
|                                    |   |                |                   |               |  |  | Epirubicin Kabi (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)       | PK |
|                                    |   |                |                   |               |  |  | Epirubicin Kabi (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)          | PK |
|                                    |   |                |                   |               |  |  | Hospira Pty Limited (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)     | HH |
|                                    |   |                |                   |               |  |  | Hospira Pty Limited (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)      | HH |
|                                    |   |                |                   |               |  |  | Pharmorubicin Solution (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)   | PF |
| <b>IDARUBICIN</b>                  |   |                |                   |               |  |  |   |    |
| <b><u>Restricted benefit</u></b>   |   |                |                   |               |  |  |   |    |
| Acute myelogenous leukaemia        |   |                |                   |               |  |  |   |    |
| 7247K                              | Injection   | 30 mg          | 5                 | ..            | *926.00  | 36.10  | Idarubicin Ebewe (idarubicin hydrochloride 10 mg/10 mL injection, 1 x 10 mL vial)         | SZ |
|                                    |   |                |                   |               |  |  | Idarubicin Ebewe (idarubicin hydrochloride 5 mg/5 mL injection, 1 x 5 mL vial)            | SZ |
|                                    |   |                |                   |               |  |  | Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6) | PF |
|                                    |   |                |                   |               |  |  | Zavedos Solution (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3)   | PF |
| <b>MITOZANTRONE</b>                |   |                |                   |               |  |  |   |    |
| 7252Q                              | Injection   | 30 mg          | 5                 | ..            | *307.75  | 36.10  | Hospira Pty Limited (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)                  | HH |
|                                    |   |                |                   |               |  |  | Mitozantrone Ebewe (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)                   | SZ |
|                                    |   |                |                   |               |  |  | Onkotrone (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)                            | BX |
|                                    |   |                |                   |               |  |  | Onkotrone (mitozantrone 25 mg/12.5 mL injection, 1 x 12.5 mL vial)                        | BX |
|                                    |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial)             | PF |
| <b>OTHER ANTINEOPLASTIC AGENTS</b> |   |                |                   |               |  |  |   |    |
| <b><i>Platinum compounds</i></b>   |   |                |                   |               |  |  |   |    |
| <b>CARBOPLATIN</b>                 |   |                |                   |               |  |  |   |    |
| 7222D                              | Injection   | 900 mg         | 5                 | ..            | *159.15  | 36.10  | Carboplatin Ebewe (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)                    | SZ |
|                                    |   |                |                   |               |  |  | Carboplatin Ebewe (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)                    | SZ |
|                                    |   |                |                   |               |  |  | Carboplatin Ebewe (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)                       | SZ |
|                                    |   |                |                   |               |  |  | Carboplatin Kabi (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)                     | PK |
|                                    |   |                |                   |               |  |  | Hospira Pty Limited (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)                  | HH |
|                                    |   |                |                   |               |  |  | Hospira Pty Limited (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)                  | HH |
|                                    |   |                |                   |               |  |  | Hospira Pty Limited (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)                     | HH |
|                                    |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)             | PF |
|                                    |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)             | PF |
| <b>CISPLATIN</b>                   |   |                |                   |               |  |  |   |    |

## Chemotherapy Items for Private Hospital/Private Clinic use

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|-------|---|----------------|-------------------|---------------|--|--|---|----|
| 7224F | Injection   | 220 mg         | 14                | ..            | *118.17  | 36.10  | Cisplatin Ebewe (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)          | SZ |
|       |   |                |                   |               |  |  | Hospira Pty Limited (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)      | HH |
|       |   |                |                   |               |  |  | Hospira Pty Limited (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)         | HH |
|       |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial) | PF |
|       |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)    | PF |

### OXALIPLATIN

#### Authority required (STREAMLINED)

**3930**

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

#### Authority required (STREAMLINED)

**3939**

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

#### Authority required (STREAMLINED)

**3900**

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

#### Authority required (STREAMLINED)

**3901**

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

#### Note

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

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

#### Note

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

#### Note

Pharmaceutical benefits that have the form oxaliplatin powder for I.V. infusion 100 mg (after reconstitution) and pharmaceutical benefits that have the form oxaliplatin solution concentrate for I.V. infusion 100 mg are equivalent for the purposes of substitution.

|       |           |        |    |    |         |       |  |    |
|-------|-----------|--------|----|----|---------|-------|--|----|
| 7253R | Injection | 300 mg | 11 | .. | *328.25 | 36.10 | AS-Oxaliplatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)              | YA |
|       |           |        |    |    |         |       | AS-Oxaliplatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)              | YA |
|       |           |        |    |    |         |       | AS-Oxaliplatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)               | YA |
|       |           |        |    |    |         |       | DBL Oxaliplatin Concentrate (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) | HH |
|       |           |        |    |    |         |       | DBL Oxaliplatin Concentrate (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)  | HH |
|       |           |        |    |    |         |       | Eloxatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)                    | SW |
|       |           |        |    |    |         |       | Eloxatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)                    | SW |
|       |           |        |    |    |         |       | Eloxatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)                     | SW |
|       |           |        |    |    |         |       | Hospira Pty Limited (oxaliplatin 100 mg injection, 1 x 100 mg vial)              | HH |
|       |           |        |    |    |         |       | Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial)                | HH |
|       |           |        |    |    |         |       | Oxaliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)                  | WQ |
|       |           |        |    |    |         |       | Oxaliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)                   | WQ |
|       |           |        |    |    |         |       | Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial)              | TA |
|       |           |        |    |    |         |       | Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial)                | TA |
|       |           |        |    |    |         |       | Oxaliplatin Alphapharm (oxaliplatin 100 mg injection, 1 x 100 mg vial)           | AF |
|       |           |        |    |    |         |       | Oxaliplatin Alphapharm (oxaliplatin 50 mg injection, 1 x 50 mg vial)             | AF |

## Chemotherapy Items for Private Hospital/Private Clinic use

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

### Monoclonal antibodies

#### BEVACIZUMAB

##### Authority required

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

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

##### Authority required

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

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

##### Note

Special Pricing Arrangements apply.

##### Note

Not for use as monotherapy.

|       |           |        |    |    |          |       |  |    |
|-------|-----------|--------|----|----|----------|-------|--|----|
| 7243F | Injection | 900 mg | 11 | .. | *4000.81 | 36.10 | Avastin (bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial)   | RO |
|       |           |        |    |    |          |       | Avastin (bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial) | RO |

#### CETUXIMAB

##### Authority required

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

##### Authority required

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

##### Note

No applications for repeats will be authorised.

|       |           |        |    |    |          |       |  |    |
|-------|-----------|--------|----|----|----------|-------|--|----|
| 7223E | Injection | 880 mg | .. | .. | *3211.49 | 36.10 | Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)   | SG |
|       |           |        |    |    |          |       | Erbix (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) | SG |

#### CETUXIMAB

##### Authority required

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

##### Note

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

|       |           |        |   |    |          |       |  |    |
|-------|-----------|--------|---|----|----------|-------|--|----|
| 7240C | Injection | 550 mg | 5 | .. | *2169.04 | 36.10 | Erbix (cetuximab 100 mg/20 mL injection, 1 x | SG |
|-------|-----------|--------|---|----|----------|-------|--|----|

## Chemotherapy Items for Private Hospital/Private Clinic use

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|--|---|----------------|-------------------|---------------|--|--|---|----------|
|  |   |                |                   |               |  |  | 20 mL vial)<br>Erbitux (cetuximab 500 mg/100 mL injection, 1<br>x 100 mL vial)  | SG       |
| <b>CETUXIMAB</b>   |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| 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                                  |   |                |                   |               |  |  |   |          |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |   |          |
| Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.  |   |                |                   |               |  |  |   |          |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |   |          |
| Special Pricing Arrangements apply.  |   |                |                   |               |  |  |   |          |
| 7242E  | Injection   | 880 mg         | ..                | ..            | *3211.49                                       | 36.10  | Erbitux (cetuximab 100 mg/20 mL injection, 1 x<br>20 mL vial)<br>Erbitux (cetuximab 500 mg/100 mL injection, 1<br>x 100 mL vial)  | SG<br>SG |
| <b>CETUXIMAB</b>   |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| 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 |   |                |                   |               |  |  |   |          |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |   |          |
| Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.  |   |                |                   |               |  |  |   |          |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |   |          |
| Special Pricing Arrangements apply.  |   |                |                   |               |  |  |   |          |
| 7273T  | Injection   | 550 mg         | 11                | ..            | *2169.04                                       | 36.10  | Erbitux (cetuximab 100 mg/20 mL injection, 1 x<br>20 mL vial)<br>Erbitux (cetuximab 500 mg/100 mL injection, 1<br>x 100 mL vial)  | SG<br>SG |
| <b>RITUXIMAB</b>   |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma   |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma  |   |                |                   |               |  |  |   |          |
| 7257Y  | Injection   | 800 mg         | 3                 | ..            | *3759.35                                       | 36.10  | Mabthera (rituximab 100 mg/10 mL injection, 2<br>x 10 mL vials)<br>Mabthera (rituximab 500 mg/50 mL injection, 1<br>x 50 mL vial) | RO<br>RO |
| <b>RITUXIMAB</b>   |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy  |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy   |   |                |                   |               |  |  |   |          |
| 7258B  | Injection   | 800 mg         | 7                 | ..            | *3759.35                                       | 36.10  | Mabthera (rituximab 100 mg/10 mL injection, 2<br>x 10 mL vials)<br>Mabthera (rituximab 500 mg/50 mL injection, 1<br>x 50 mL vial) | RO<br>RO |
| <b>RITUXIMAB</b>   |   |                |                   |               |  |  |   |          |
| <b><u>Authority required</u></b>   |   |                |                   |               |  |  |   |          |
| CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide   |   |                |                   |               |  |  |   |          |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |   |          |
| Rituximab is not PBS-subsidised for use as monotherapy.  |   |                |                   |               |  |  |   |          |
| 7259C  | Injection   | 1100 mg        | 5                 | ..            | *5109.25                                       | 36.10  | Mabthera (rituximab 100 mg/10 mL injection, 2<br>x 10 mL vials)   | RO       |

## Chemotherapy Items for Private Hospital/Private Clinic use

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|------|---|-------------|-------------|------------|------------------------------------|--|--|
|      |   |             |             |            |                                    |  | Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial) RO |

### TRASTUZUMAB

#### **Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

#### **The Clinical criteria is:**

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:
  - (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
  - (ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 4 mg per kg.

#### **Authority required**

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

#### **The Clinical criteria is:**

Patient must commence treatment concurrently with adjuvant chemotherapy,

#### **AND the Clinical criteria is:**

Patient must have undergone surgery,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:
  - (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
  - (ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 4 mg per kg.

#### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                               |    |
|-------|---|----------------|-------------------|---------------|--|--|---|----|
|       | Prior Written Approval of Complex Drugs           |                |                   |               |  |  |   |    |
|       | Reply Paid 9826                                   |                |                   |               |  |  |   |    |
|       | GPO Box 9826                                      |                |                   |               |  |  |   |    |
|       | HOBART TAS 7001                                   |                |                   |               |  |  |   |    |
| 7264H | Injection   | 500 mg         | ..                | ..            | *3613.52                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) | RO |
|       |   |                |                   |               |  |  | Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)   | RO |

### **TRASTUZUMAB**

#### **Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 2 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### **Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 2 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### **Note**

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

#### **Note**

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

#### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

## Chemotherapy Items for Private Hospital/Private Clinic use

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|-------|---|----------------|-------------------|---------------|--|--|--|
|       | GPO Box 9826<br>HOBART TAS 7001                   |                |                   |               |  |  |  |
| 7265J | Injection   | 250 mg         | 9                 | ..            | *1966.74                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) RO<br>Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) RO |

### TRASTUZUMAB

#### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

#### The Clinical criteria is:

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

#### AND the Clinical criteria is:

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

#### AND the Clinical criteria is:

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

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

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

(a) a completed authority prescription form; and

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

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

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

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 8 mg per kg.

#### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

#### The Clinical criteria is:

Patient must commence treatment concurrently with adjuvant chemotherapy,

#### AND the Clinical criteria is:

Patient must have undergone surgery,

#### AND the Clinical criteria is:

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

#### AND the Clinical criteria is:

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

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

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

(a) a completed authority prescription form; and

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

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

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

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 8 mg per kg.

#### Note

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

## Chemotherapy Items for Private Hospital/Private Clinic use

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|---|---|----------------|-------------------|---------------|--|--|--|
| Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> |   |                |                   |               |  |  |  |
| Applications for authority to prescribe should be forwarded to:<br>Department of Human Services<br>Prior Written Approval of Complex Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001  |   |                |                   |               |  |  |  |
| 7266K   | Injection   | 1000 mg        | ..                | ..            | *7120.75                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) RO<br>Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) RO |

### TRASTUZUMAB

#### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### The Clinical criteria is:

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

#### AND the Clinical criteria is:

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

#### AND the Clinical criteria is:

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

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

For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 6 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### The Clinical criteria is:

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

#### AND the Clinical criteria is:

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

#### AND the Clinical criteria is:

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

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

For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 6 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### Note

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

#### Note

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

#### Note

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

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

Applications for authority to prescribe should be forwarded to:

## Chemotherapy Items for Private Hospital/Private Clinic use

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|-------|---|----------------|-------------------|---------------|--|--|---|----|
|       | Department of Human Services                      |                |                   |               |  |  |   |    |
|       | Prior Written Approval of Complex Drugs           |                |                   |               |  |  |   |    |
|       | Reply Paid 9826                                   |                |                   |               |  |  |   |    |
|       | GPO Box 9826                                      |                |                   |               |  |  |   |    |
|       | HOBART TAS 7001                                   |                |                   |               |  |  |   |    |
| 7267L | Injection   | 750 mg         | 3                 | ..            | *5266.18                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) | RO |
|       |   |                |                   |               |  |  | Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)   | RO |

### Other antineoplastic agents

#### ARSENIC

##### Authority required

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

|       |           |       |    |    |         |       |   |    |
|-------|-----------|-------|----|----|---------|-------|---|----|
| 7241D | Injection | 18 mg | 89 | .. | *910.09 | 36.10 | Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) | PL |
|-------|-----------|-------|----|----|---------|-------|---|----|

#### BORTEZOMIB

##### Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

##### The Clinical criteria is:

Patient must be newly diagnosed,

##### AND the Clinical criteria is:

Patient must be ineligible for high dose chemotherapy,

##### AND the Clinical criteria is:

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

##### AND the Clinical criteria is:

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

##### AND the Clinical criteria is:

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma and ineligibility for high dose chemotherapy; and
- (3) a signed patient acknowledgement.

##### Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

##### The Clinical criteria is:

Patient must be newly diagnosed,

##### AND the Clinical criteria is:

Patient must have severe acute renal failure,

##### AND the Clinical criteria is:

Patient must require dialysis; OR

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

##### AND the Clinical criteria is:

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

##### AND the Clinical criteria is:

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

##### AND the Clinical criteria is:

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

## Chemotherapy Items for Private Hospital/Private Clinic use

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

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

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

Disease activity parameters include current diagnostic reports of at least one of the following:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided.

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

### **Note**

Patients who have initiated treatment with thalidomide within the last month do not have to experience failure after a trial of at least 4 weeks of thalidomide or to have failed to achieve at least a minimal response after at least 8 weeks of thalidomide treatment.

### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

### **Note**

Special Pricing Arrangements apply.

|       |           |          |    |    |          |       |  |    |
|-------|-----------|----------|----|----|----------|-------|--|----|
| 7238Y | Injection | 3000 mcg | 31 | .. | *1604.27 | 36.10 | Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) | JC |
|-------|-----------|----------|----|----|----------|-------|--|----|

### **BORTEZOMIB**

#### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The condition must be confirmed by a histological diagnosis,

#### **AND the Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

## Chemotherapy Items for Private Hospital/Private Clinic use

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

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

**AND the Clinical criteria is:**

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

**AND the Clinical criteria is:**

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

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

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

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

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

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

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

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

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

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

**Authority required**

Multiple myeloma

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

**The Clinical criteria is:**

## Chemotherapy Items for Private Hospital/Private Clinic use

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|-------|--|----------------|-------------------|---------------|--|--|---|
|       | <p>The treatment must be as monotherapy; OR</p> <p>The treatment must be in combination with a corticosteroid and/or cyclophosphamide,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must have previously received 4 treatment cycles of bortezomib for progressive disease,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must not have a gap of more than 6 months between the initial application and subsequent applications,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and</p> <p>(3) diagnostic reports demonstrating the patient has achieved at least a partial response.</p> <p>If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).</p> <p>If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.</p> <p>If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.</p> <p>If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(a) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or</p> <p>(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.</p> <p>Diagnostic reports must be no more than one month old at the time of application.</p> <p>Where a response assessment is not submitted prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib.</p> <p>Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.</p> <p><b>Note</b></p> <p>Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.</p> <p><b>Note</b></p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services<br/>Prior Written Approval of Complex Drugs<br/>Reply Paid 9826<br/>GPO Box 9826<br/>HOBART TAS 7001</p> <p><b>Note</b></p> <p>Special Pricing Arrangements apply.</p> |                |                   |               |  |  |   |
| 7268M | Injection  | 3000 mcg       | 15                | ..            | *1858.93                                       | 36.10  | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC |

**BORTEZOMIB**  
**Authority required**

## Chemotherapy Items for Private Hospital/Private Clinic use

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|-------|--|----------------|-------------------|---------------|--|--|---|
|       | <b>Multiple myeloma</b>  |                |                   |               |  |  |   |
|       | Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment  |                |                   |               |  |  |   |
|       | <b>The Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | The treatment must be as monotherapy; OR   |                |                   |               |  |  |   |
|       | The treatment must be in combination with a corticosteroid and/or cyclophosphamide,  |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must have previously received 8 treatment cycles of bortezomib for progressive disease,  |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles,  |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must not receive more than 3 cycles of bortezomib under this restriction.  |                |                   |               |  |  |   |
|       | The authority application must be made in writing and must include:  |                |                   |               |  |  |   |
|       | (1) a completed authority prescription form; and   |                |                   |               |  |  |   |
|       | (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and   |                |                   |               |  |  |   |
|       | (3) diagnostic reports demonstrating the patient has achieved at least a partial response.   |                |                   |               |  |  |   |
|       | If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).   |                |                   |               |  |  |   |
|       | If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. |                |                   |               |  |  |   |
|       | If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.                                   |                |                   |               |  |  |   |
|       | If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:  |                |                   |               |  |  |   |
|       | (a) at least a 50% reduction in bone marrow plasma cells; or   |                |                   |               |  |  |   |
|       | (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or  |                |                   |               |  |  |   |
|       | (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or   |                |                   |               |  |  |   |
|       | (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.   |                |                   |               |  |  |   |
|       | Diagnostic reports must be no more than one month old at the time of application.  |                |                   |               |  |  |   |
|       | Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib.   |                |                   |               |  |  |   |
|       | Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.  |                |                   |               |  |  |   |
|       | <b>Note</b>  |                |                   |               |  |  |   |
|       | Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).   |                |                   |               |  |  |   |
|       | Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>  |                |                   |               |  |  |   |
|       | Applications for authority to prescribe should be forwarded to:  |                |                   |               |  |  |   |
|       | Department of Human Services   |                |                   |               |  |  |   |
|       | Prior Written Approval of Complex Drugs  |                |                   |               |  |  |   |
|       | Reply Paid 9826  |                |                   |               |  |  |   |
|       | GPO Box 9826   |                |                   |               |  |  |   |
|       | HOBART TAS 7001  |                |                   |               |  |  |   |
|       | <b>Note</b>  |                |                   |               |  |  |   |
|       | Special Pricing Arrangements apply.  |                |                   |               |  |  |   |
| 7269N | Injection  | 3000 mcg       | 11                | ..            | *1858.93                                       | 36.10  | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC |

**BORTEZOMIB**  
**Authority required**

## Chemotherapy Items for Private Hospital/Private Clinic use

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|------|--|----------------|-------------------|---------------|--|--|-----------------------------|
|      | <b>Multiple myeloma</b>  |                |                   |               |  |  |                             |
|      | Treatment Phase: Retreatment of Progressive disease - Initial PBS-subsidised treatment   |                |                   |               |  |  |                             |
|      | <b>The Clinical criteria is:</b>   |                |                   |               |  |  |                             |
|      | The treatment must be as monotherapy; OR   |                |                   |               |  |  |                             |
|      | The treatment must be in combination with a corticosteroid and/or cyclophosphamide,  |                |                   |               |  |  |                             |
|      | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |                             |
|      | Patient must have progressive disease,   |                |                   |               |  |  |                             |
|      | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |                             |
|      | Patient must have previously been treated with PBS-subsidised bortezomib,  |                |                   |               |  |  |                             |
|      | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |                             |
|      | Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy,  |                |                   |               |  |  |                             |
|      | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |                             |
|      | Patient must not be receiving concomitant PBS-subsidised lenalidomide,   |                |                   |               |  |  |                             |
|      | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |                             |
|      | Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.   |                |                   |               |  |  |                             |
|      | Progressive disease is defined as at least 1 of the following:   |                |                   |               |  |  |                             |
|      | (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or   |                |                   |               |  |  |                             |
|      | (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or   |                |                   |               |  |  |                             |
|      | (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or  |                |                   |               |  |  |                             |
|      | (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or   |                |                   |               |  |  |                             |
|      | (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  |                |                   |               |  |  |                             |
|      | (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or   |                |                   |               |  |  |                             |
|      | (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  |                |                   |               |  |  |                             |
|      | Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.   |                |                   |               |  |  |                             |
|      | If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).   |                |                   |               |  |  |                             |
|      | If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. |                |                   |               |  |  |                             |
|      | If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.                                   |                |                   |               |  |  |                             |
|      | If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:  |                |                   |               |  |  |                             |
|      | (a) at least a 50% reduction in bone marrow plasma cells; or   |                |                   |               |  |  |                             |
|      | (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or  |                |                   |               |  |  |                             |
|      | (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or   |                |                   |               |  |  |                             |
|      | (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.   |                |                   |               |  |  |                             |
|      | The authority application must be made in writing and must include:  |                |                   |               |  |  |                             |
|      | (1) a completed authority prescription form; and   |                |                   |               |  |  |                             |
|      | (2) a completed Multiple Myeloma bortezomib Authority Application - Supporting Information Form which includes details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and                     |                |                   |               |  |  |                             |
|      | (3) diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously provided; and  |                |                   |               |  |  |                             |
|      | (4) a signed patient acknowledgment.   |                |                   |               |  |  |                             |
|      | To enable confirmation of eligibility for treatment current diagnostic reports of at least one of the following must be provided:  |                |                   |               |  |  |                             |
|      | (a) the level of serum monoclonal protein; or  |                |                   |               |  |  |                             |
|      | (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or   |                |                   |               |  |  |                             |
|      | (c) the serum level of free kappa and lambda light chains; or  |                |                   |               |  |  |                             |
|      | (d) bone marrow aspirate or trephine; or   |                |                   |               |  |  |                             |
|      | (e) if present, the size and location of lytic bone lesions (not including compression fractures); or  |                |                   |               |  |  |                             |

## Chemotherapy Items for Private Hospital/Private Clinic use

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

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

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

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

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

### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
- (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

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

### **Note**

Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction,<br>Manner of<br>Administration  | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                               |
|-------|--|----------------|-------------------|---------------|--|--|---|
|       | Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001 |                |                   |               |  |  |   |
|       | <b>Note</b><br>Special Pricing Arrangements apply. |                |                   |               |  |  |   |
| 7271Q | Injection  | 3000 mcg       | 15                | ..            | *1858.93                                       | 36.10  | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC |

### **BORTEZOMIB**

#### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
- (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

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

#### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction,<br>Manner of<br>Administration  | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                               |
|-------|--|----------------|-------------------|---------------|--|--|---|
|       | Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001 |                |                   |               |  |  |   |
|       | <b>Note</b><br>Special Pricing Arrangements apply. |                |                   |               |  |  |   |
| 7272R | Injection  | 3000 mcg       | 11                | ..            | *1858.93                                       | 36.10  | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC |

### **BORTEZOMIB**

#### **Authority required**

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

#### **Note**

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

#### **Authority required**

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form, which includes a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

## Chemotherapy Items for Private Hospital/Private Clinic use

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

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are not being used to monitor disease activity, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
- (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

### **Note**

Authority applications for continuing treatment may be faxed to the Department of Human Services on 1300 154 190 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

### **Note**

Special Pricing Arrangements apply.

|       |           |          |    |    |          |       |  |    |
|-------|-----------|----------|----|----|----------|-------|--|----|
| 7274W | Injection | 3000 mcg | 19 | .. | *1604.27 | 36.10 | Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) | JC |
|-------|-----------|----------|----|----|----------|-------|--|----|

### **BORTEZOMIB**

#### **Authority required**

Symptomatic multiple myeloma

#### **The Clinical criteria is:**

Patient must be newly diagnosed,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

The treatment must be in combination with chemotherapy,

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma; and
- (3) a signed patient acknowledgement.

### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code  | Name, Restriction,<br>Manner of<br>Administration   | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer   |    |
|-------|---|----------------|-------------------|---------------|--|--|---|----|
|       | Prior Written Approval of Complex Drugs   |                |                   |               |  |  |   |    |
|       | Reply Paid 9826   |                |                   |               |  |  |   |    |
|       | GPO Box 9826  |                |                   |               |  |  |   |    |
|       | HOBART TAS 7001   |                |                   |               |  |  |   |    |
|       | <b>Note</b>   |                |                   |               |  |  |   |    |
|       | Special Pricing Arrangements apply.   |                |                   |               |  |  |   |    |
| 7275X | Injection   | 3000 mcg       | 15                | ..            | *1604.27                                       | 36.10  | Velcade (bortezomib 1 mg injection, 1 x 1 mg vial)  | JC |
|       | <b>IRINOTECAN</b>   |                |                   |               |  |  |   |    |
|       | <b>Authority required (STREAMLINED)</b>   |                |                   |               |  |  |   |    |
|       | <b>3184</b>   |                |                   |               |  |  |   |    |
|       | Metastatic colorectal cancer in patients with a WHO performance status of 2 or less   |                |                   |               |  |  |   |    |
|       | <b>Note</b>   |                |                   |               |  |  |   |    |
|       | In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen. |                |                   |               |  |  |   |    |
| 7249M | Injection   | 800 mg         | 11                | ..            | *396.25  | 36.10  | Camptosar (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)              | PF |
|       |   |                |                   |               |  |  | Hospira Pty Limited (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)      | HH |
|       |   |                |                   |               |  |  | Hospira Pty Limited (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)       | HH |
|       |   |                |                   |               |  |  | Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)    | HH |
|       |   |                |                   |               |  |  | Irinoccord (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)               | WQ |
|       |   |                |                   |               |  |  | Irinoccord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)                | WQ |
|       |   |                |                   |               |  |  | Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)       | TA |
|       |   |                |                   |               |  |  | Irinotecan Actavis (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)        | TA |
|       |   |                |                   |               |  |  | Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) | TA |
|       |   |                |                   |               |  |  | Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)    | AF |
|       |   |                |                   |               |  |  | Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)     | AF |
|       |   |                |                   |               |  |  | Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)  | AF |
|       |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)         | SZ |
|       |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)       | SZ |
|       |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)          | SZ |
|       |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)       | SZ |
|       |   |                |                   |               |  |  | Irinotecan Kabi (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)          | PK |
|       |   |                |                   |               |  |  | Irinotecan Kabi (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)           | PK |

## Chemotherapy Items for Private Hospital/Private Clinic use

| Code | Name, Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer  |    |
|------|---|----------------|-------------------|---------------|--|--|--|----|
|      |   |                |                   |               |  |  | Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) | OE |
|      |   |                |                   |               |  |  | Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)  | OE |
|      |   |                |                   |               |  |  | Tecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)                 | WQ |
|      |   |                |                   |               |  |  | Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)                  | WQ |
|      |   |                |                   |               |  |  | Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)               | WQ |

### TOPOTECAN

#### Authority required (STREAMLINED)

**3186**

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

|       |           |          |    |    |         |       |   |    |
|-------|-----------|----------|----|----|---------|-------|---|----|
| 7260D | Injection | 3500 mcg | 17 | .. | *424.77 | 36.10 | Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials)       | GK |
|       |           |          |    |    |         |       | Topotecan Agila (topotecan 4 mg injection, 1 x 4 mg vial) | YA |
|       |           |          |    |    |         |       | Topotecan Kabi (topotecan 4 mg injection, 5 x 4 mg vials) | PK |



## **CHEMOTHERAPY ITEMS FOR PUBLIC HOSPITAL USE**

### Special Pharmaceutical Benefits for Public Hospital use

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 32.

| Code | Name,<br>Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Total<br>Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Proposed<br>Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer |
|------|--|----------------|-------------------|---------------|---|--|--|-----------------------------|
|------|--|----------------|-------------------|---------------|---|--|--|-----------------------------|

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ANTINEOPLASTIC AGENTS

#### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

##### *Other cytotoxic antibiotics*

##### BLEOMYCIN SULFATE

##### Restricted benefit

Germ cell neoplasms

##### Restricted benefit

Lymphoma

|       |           |          |    |         |         |         |       |   |          |
|-------|-----------|----------|----|---------|---------|---------|-------|---|----------|
| 4433H | Injection | 30000 iu | 11 | \$61.78 | *109.34 | *171.12 | 36.10 | Bleo 15K (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial)<br>Hospira Pty Limited (bleomycin sulfate 15 000 international units injection, 1 x 15 000 international units vial) | WQ<br>HH |
|-------|-----------|----------|----|---------|---------|---------|-------|---|----------|

## Chemotherapy Items for Public Hospital use

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

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ANTINEOPLASTIC AGENTS

### ALKYLATING AGENTS

#### *Nitrogen mustard analogues*

##### CYCLOPHOSPHAMIDE

|       |           |         |    |    |         |       |  |    |
|-------|-----------|---------|----|----|---------|-------|--|----|
| 4327R | Injection | 2800 mg | 17 | .. | *104.27 | 36.10 | Endoxan (cyclophosphamide 1 g injection, 1 x 1 g vial)       | BX |
|       |           |         |    |    |         |       | Endoxan (cyclophosphamide 2 g injection, 1 x 2 g vial)       | BX |
|       |           |         |    |    |         |       | Endoxan (cyclophosphamide 500 mg injection, 1 x 500 mg vial) | BX |

##### IFOSFAMIDE

##### Restricted benefit

Relapsed or refractory germ cell tumours following first-line chemotherapy

##### Restricted benefit

Relapsed or refractory sarcomas following first-line chemotherapy

|       |           |         |    |    |         |       |  |    |
|-------|-----------|---------|----|----|---------|-------|--|----|
| 4448D | Injection | 4000 mg | 19 | .. | *277.24 | 36.10 | Holoxan (ifosfamide 1 g injection, 1 x 1 g vial) | BX |
|       |           |         |    |    |         |       | Holoxan (ifosfamide 2 g injection, 1 x 2 g vial) | BX |

#### *Nitrosoureas*

##### FOTEMUSTINE

##### Authority required (STREAMLINED)

**3181**

Metastatic malignant melanoma

|       |           |        |   |    |          |       |  |    |
|-------|-----------|--------|---|----|----------|-------|--|----|
| 4437M | Injection | 220 mg | 8 | .. | *2209.30 | 36.10 | Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&) inert substance diluent [1 x 4 mL ampoule], 1 pack) | SE |
|-------|-----------|--------|---|----|----------|-------|--|----|

### ANTIMETABOLITES

#### *Folic acid analogues*

##### METHOTREXATE

|       |           |        |   |    |        |       |  |    |
|-------|-----------|--------|---|----|--------|-------|--|----|
| 4502Y | Injection | 250 mg | 5 | .. | *59.44 | 36.10 | Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)       | HH |
|       |           |        |   |    |        |       | Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)       | HH |
|       |           |        |   |    |        |       | Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)      | HH |
|       |           |        |   |    |        |       | Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)    | HH |
|       |           |        |   |    |        |       | Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)                         | WQ |
|       |           |        |   |    |        |       | Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)                | WQ |
|       |           |        |   |    |        |       | Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)        | SZ |
|       |           |        |   |    |        |       | Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)        | SZ |
|       |           |        |   |    |        |       | Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) | PF |

##### METHOTREXATE

##### Restricted benefit

Patients receiving treatment with a high dose regimen.

|       |           |          |    |    |          |       |   |    |
|-------|-----------|----------|----|----|----------|-------|---|----|
| 4512L | Injection | 20000 mg | .. | .. | *1544.24 | 36.10 | Hospira Pty Limited (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)  | HH |
|       |           |          |    |    |          |       | Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)  | HH |
|       |           |          |    |    |          |       | Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) | HH |

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer  |    |
|---|---|----------------|-------------------|---------------|--|--|--|----|
|   |   |                |                   |               |  |  | Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial)    | HH |
|   |   |                |                   |               |  |  | Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1)                         | WQ |
|   |   |                |                   |               |  |  | Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)                | WQ |
|   |   |                |                   |               |  |  | Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial)        | SZ |
|   |   |                |                   |               |  |  | Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial)        | SZ |
|   |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) | PF |
| <b>PEMETREXED</b>   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3885</b>   |   |                |                   |               |  |  |  |    |
| 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  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3886</b>   |   |                |                   |               |  |  |  |    |
| Mesothelioma in combination with cisplatin.   |   |                |                   |               |  |  |  |    |
| Doses greater than 500 mg per metre squared body surface area (BSA) are not PBS-subsidised. The patient's BSA must be documented in the patient's medical records at the time the treatment cycle is initiated  |   |                |                   |               |  |  |  |    |
| 4600D   | Injection   | 1100 mg        | 5                 | ..            | *3472.31                                       | 36.10  | Alimta (pemetrexed 100 mg injection, 1 x 100 mg vial)                        | LY |
|   |   |                |                   |               |  |  | Alimta (pemetrexed 500 mg injection, 1 x 500 mg vial)                        | LY |
| <b>RALTITREXED</b>  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3185</b>   |   |                |                   |               |  |  |  |    |
| For use as a single agent in the treatment of advanced colorectal cancer  |   |                |                   |               |  |  |  |    |
| 4610P   | Injection   | 7 mg           | 8                 | ..            | *1054.00                                       | 36.10  | Tomudex (raltitrexed 2 mg injection, 1 x 2 mg vial)                          | HH |
| <b>Purine analogues</b>   |   |                |                   |               |  |  |  |    |
| <b>CLADRIBINE</b>   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3180</b>   |   |                |                   |               |  |  |  |    |
| Hairy cell leukaemia  |   |                |                   |               |  |  |  |    |
| 4326Q   | Injection   | 17 mg          | 6                 | ..            | *1321.56                                       | 36.10  | Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial)                 | JC |
|   |   |                |                   |               |  |  | Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial)                       | OA |
| <b>FLUDARABINE</b>  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3887</b>   |   |                |                   |               |  |  |  |    |
| 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  |   |                |                   |               |  |  |  |    |
| <b>Note</b>   |   |                |                   |               |  |  |  |    |
| Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical benefits that have the form fludarabine phosphate solution for I.V. injection 50 mg are equivalent for the purposes of substitution.   |   |                |                   |               |  |  |  |    |
| 4393F   | Injection   | 55 mg          | 29                | ..            | *589.12  | 36.10  | AS-Fludarabine (fludarabine phosphate 50 mg/2 mL injection, 1 x 2 mL vial)   | YA |
|   |   |                |                   |               |  |  | Farine (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)               | WQ |

## Chemotherapy Items for Public Hospital use

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|--|---|----------------|-------------------|---------------|--|--|--|----|
|  |   |                |                   |               |  |  | Fludara (fludarabine phosphate 50 mg injection, 5 x 50 mg vials)                   | GZ |
|  |   |                |                   |               |  |  | Fludarabine Actavis (fludarabine phosphate 50 mg injection, 1 x 50 mg vial)        | TA |
|  |   |                |                   |               |  |  | Fludarabine Ebewe (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)     | SZ |
| <b>Pyrimidine analogues</b>  |   |                |                   |               |  |  |  |    |
| <b>CYTARABINE</b>  |   |                |                   |               |  |  |  |    |
| 4357H  | Injection   | 7000 mg        | 15                | ..            | *746.94  | 36.10  | Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)        | PF |
| <b>FLUOROURACIL</b>  |   |                |                   |               |  |  |  |    |
| <b>Restricted benefit</b>  |   |                |                   |               |  |  |  |    |
| For patients requiring administration of fluorouracil by intravenous infusion.   |   |                |                   |               |  |  |  |    |
| 4394G  | Injection   | 5500 mg        | 11                | ..            | *78.81   | 36.10  | DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)  | HH |
|  |   |                |                   |               |  |  | DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) | HH |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)              | SZ |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)            | SZ |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)            | SZ |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)          | SZ |
|  |   |                |                   |               |  |  | Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)         | HH |
| <hr/>  |   |                |                   |               |  |  |  |    |
| <b>FLUOROURACIL</b>  |   |                |                   |               |  |  |  |    |
| <b>Restricted benefit</b>  |   |                |                   |               |  |  |  |    |
| For patients requiring administration of fluorouracil by intravenous injection.  |   |                |                   |               |  |  |  |    |
| 4431F  | Injection   | 1000 mg        | 23                | ..            | *47.58   | 36.10  | DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials)  | HH |
|  |   |                |                   |               |  |  | DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) | HH |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 1 g/20 mL injection, 1 x 20 mL vial)              | SZ |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial)            | SZ |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 5 g/100 mL injection, 1 x 100 mL vial)            | SZ |
|  |   |                |                   |               |  |  | Fluorouracil Ebewe (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)          | SZ |
|  |   |                |                   |               |  |  | Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)         | HH |
| <b>GEMCITABINE</b>   |   |                |                   |               |  |  |  |    |
| <b>Caution</b>   |   |                |                   |               |  |  |  |    |
| Pharmaceutical benefits containing gemcitabine may have different concentrations.  |   |                |                   |               |  |  |  |    |
| <b>Note</b>  |   |                |                   |               |  |  |  |    |
| Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL, gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL and gemcitabine solution for injection 200 mg (as hydrochloride) in 5.3 mL are equivalent for the purposes of substitution. |   |                |                   |               |  |  |  |    |
| <b>Note</b>  |   |                |                   |               |  |  |  |    |
| Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL, gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL and gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution.      |   |                |                   |               |  |  |  |    |
| <b>Note</b>  |   |                |                   |               |  |  |  |    |
| Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL and gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.   |   |                |                   |               |  |  |  |    |
| 4439P  | Injection   | 3000 mg        | 17                | ..            | *223.07  | 36.10  | AS-Gemcitabine (gemcitabine 1 g injection, 1 x 1 g vial)                           | YA |

## Chemotherapy Items for Public Hospital use

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|------|---|----------------|-------------------|---------------|--|--|--|----|
|      |   |                |                   |               |  |  | AS-Gemcitabine (gemcitabine 2 g injection, 1 x 2 g vial)                         | YA |
|      |   |                |                   |               |  |  | AS-Gemcitabine (gemcitabine 200 mg injection, 1 x 200 mg vial)                   | YA |
|      |   |                |                   |               |  |  | DBL Gemcitabine Injection (gemcitabine 1 g/26.3 mL injection, 1 x 26.3 mL vial)  | HH |
|      |   |                |                   |               |  |  | DBL Gemcitabine Injection (gemcitabine 2 g/52.6 mL injection, 1 x 52.6 mL vial)  | HH |
|      |   |                |                   |               |  |  | DBL Gemcitabine Injection (gemcitabine 200 mg/5.3 mL injection, 1 x 5.3 mL vial) | HH |
|      |   |                |                   |               |  |  | DBL Gemcitabine for Injection (gemcitabine 1 g injection, 1 x 1 g vial)          | HH |
|      |   |                |                   |               |  |  | DBL Gemcitabine for Injection (gemcitabine 2 g injection, 1 x 2 g vial)          | HH |
|      |   |                |                   |               |  |  | DBL Gemcitabine for Injection (gemcitabine 200 mg injection, 1 x 200 mg vial)    | HH |
|      |   |                |                   |               |  |  | Gemaccord (gemcitabine 1 g injection, 1 x 1 g vial)                              | WQ |
|      |   |                |                   |               |  |  | Gemaccord (gemcitabine 200 mg injection, 1 x 200 mg vial)                        | WQ |
|      |   |                |                   |               |  |  | Gemcitabine Actavis (gemcitabine 1 g injection, 1 x 1 g vial)                    | TA |
|      |   |                |                   |               |  |  | Gemcitabine Actavis (gemcitabine 200 mg injection, 1 x 200 mg vial)              | TA |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 1 g injection, 1 x 1 g vial)                      | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 1 g/100 mL injection, 1 x 100 mL vial)            | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 1 g/25 mL injection, 1 x 25 mL vial)              | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 2 g/50 mL injection, 1 x 50 mL vial)              | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 200 mg injection, 1 x 200 mg vial)                | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 200 mg/20 mL injection, 1 x 20 mL vial)           | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 200 mg/5 mL injection, 1 x 5 mL vial)             | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Ebewe (gemcitabine 500 mg/50 mL injection, 1 x 50 mL vial)           | SZ |
|      |   |                |                   |               |  |  | Gemcitabine Kabi (gemcitabine 1 g injection, 1 x 1 g vial)                       | PK |
|      |   |                |                   |               |  |  | Gemcitabine Kabi (gemcitabine 2 g injection, 1 x 2 g vial)                       | PK |
|      |   |                |                   |               |  |  | Gemcitabine Kabi (gemcitabine 200 mg injection, 1 x 200 mg vial)                 | PK |
|      |   |                |                   |               |  |  | Gemcitabine Sun (gemcitabine 1 g injection, 1 x 1 g vial)                        | ZF |
|      |   |                |                   |               |  |  | Gemcitabine Sun (gemcitabine 200 mg injection, 1 x 200 mg vial)                  | ZF |
|      |   |                |                   |               |  |  | Gemplan (gemcitabine 1 g injection, 1 x 1 g vial)                                | WQ |
|      |   |                |                   |               |  |  | Gemplan (gemcitabine 200 mg injection, 1 x 200 mg vial)                          | WQ |
|      |   |                |                   |               |  |  | Gemzar (gemcitabine 1 g injection, 1 x 1 g vial)                                 | LY |
|      |   |                |                   |               |  |  | Gemzar (gemcitabine 200 mg injection, 1 x 200 mg vial)                           | LY |

### PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

#### *Vinca alkaloids and analogues*

|                    |           |       |    |    |        |       |  |    |
|--------------------|-----------|-------|----|----|--------|-------|--|----|
| <b>VINBLASTINE</b> |           |       |    |    |        |       |  |    |
| 4618C              | Injection | 20 mg | 17 | .. | *95.88 | 36.10 | Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials) | HH |
| <b>VINCRIStINE</b> |           |       |    |    |        |       |  |    |
| 4619D              | Injection | 2 mg  | 7  | .. | *65.30 | 36.10 | Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)      | HH |
| <b>VINORELBINE</b> |           |       |    |    |        |       |  |    |

## Chemotherapy Items for Public Hospital use

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|---|---|-------------|-------------|------------|------------------------------------|--|---|----|
| <b><u>Authority required (STREAMLINED)</u></b>  |   |             |             |            |                                    |  |   |    |
| <b>3890</b>   |   |             |             |            |                                    |  |   |    |
| Locally advanced or metastatic non-small cell lung cancer                             |   |             |             |            |                                    |  |   |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |             |             |            |                                    |  |   |    |
| <b>3907</b>   |   |             |             |            |                                    |  |   |    |
| Advanced breast cancer after failure of prior therapy which includes an anthracycline |   |             |             |            |                                    |  |   |    |
| 4620E   | Injection                                   | 70 mg       | 7           | ..         | *178.78                            | 36.10                                      | AS-Vinorelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)        | YA |
|   |   |             |             |            |                                    |  | AS-Vinorelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)      | YA |
|   |   |             |             |            |                                    |  | Hospira Pty Limited (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)   | HH |
|   |   |             |             |            |                                    |  | Hospira Pty Limited (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) | HH |
|   |   |             |             |            |                                    |  | Navelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)             | FB |
|   |   |             |             |            |                                    |  | Navelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)           | FB |
|   |   |             |             |            |                                    |  | Vinorelbine Ebewe (vinorelbine 10 mg/mL injection, 1 x 1 mL vial)     | SZ |
|   |   |             |             |            |                                    |  | Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)   | SZ |
|   |   |             |             |            |                                    |  | Vinorelbine Kabi (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial)    | PK |

### ***Podophyllotoxin derivatives***

|                  |           |        |    |    |         |       |   |    |
|------------------|-----------|--------|----|----|---------|-------|---|----|
| <b>ETOPOSIDE</b> |           |        |    |    |         |       |   |    |
| 4428C            | Injection | 440 mg | 14 | .. | *173.44 | 36.10 | Etopophos (etoposide 1 g injection, 1 x 1 g vial)                 | BQ |
|                  |           |        |    |    |         |       | Etopophos (etoposide 100 mg injection, 1 x 100 mg vial)           | BQ |
|                  |           |        |    |    |         |       | Etoposide Ebewe (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) | SZ |

### ***Taxanes***

#### **CABAZITAXEL**

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

**4138**

Castration resistant metastatic carcinoma of the prostate

##### **The Clinical criteria is:**

The treatment must be in combination with prednisone or prednisolone,

##### **AND the Clinical criteria is:**

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

##### **AND the Clinical criteria is:**

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

##### **Note**

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

##### **Note**

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

##### **Note**

Special Pricing Arrangements apply.

|       |           |       |   |    |          |       |  |    |
|-------|-----------|-------|---|----|----------|-------|--|----|
| 4376H | Injection | 55 mg | 5 | .. | *5855.38 | 36.10 | Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1) | SW |
|-------|-----------|-------|---|----|----------|-------|--|----|

#### **DOCETAXEL**

##### **Caution**

Pharmaceutical benefits containing docetaxel may have different concentrations.

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

**3916**

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

##### **Note**

Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V.

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|--|---|----------------|-------------------|---------------|--|--|---|----|
| infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.   |   |                |                   |               |  |  |   |    |
| <b>Note</b>  |   |                |                   |               |  |  |   |    |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. |   |                |                   |               |  |  |   |    |
| 5581R  | Injection   | 250 mg         | 5                 | ..            | *931.47  | 36.10  | DBL Docetaxel Concentrated Injection<br>(docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)                    | HH |
|  |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                       | HH |
|  |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                       | HH |
|  |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)   | HX |
|  |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)   | HX |
|  |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)  | SZ |
|  |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)  | SZ |
|  |   |                |                   |               |  |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)  | TA |
|  |   |                |                   |               |  |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)  | TA |
|  |   |                |                   |               |  |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)  | TA |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)  | SW |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack) | SW |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)  | SW |

### DOCETAXEL

#### Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

#### Authority required (STREAMLINED)

3956

Treatment of HER2 positive breast cancer in combination with trastuzumab

#### Note

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

#### Note

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

|       |           |        |   |    |         |       |  |    |
|-------|-----------|--------|---|----|---------|-------|--|----|
| 5582T | Injection | 250 mg | 5 | .. | *931.47 | 36.10 | DBL Docetaxel Concentrated Injection<br>(docetaxel 160 mg/16 mL injection, 1 x 16 mL vial) | HH |
|       |           |        |   |    |         |       | DBL Docetaxel Concentrated Injection<br>(docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)    | HH |
|       |           |        |   |    |         |       | DBL Docetaxel Concentrated Injection<br>(docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)    | HH |
|       |           |        |   |    |         |       | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                           | SZ |
|       |           |        |   |    |         |       | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                           | SZ |
|       |           |        |   |    |         |       | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)                             | TA |
|       |           |        |   |    |         |       | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)                                 | TA |
|       |           |        |   |    |         |       | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)                               | TA |

## Chemotherapy Items for Public Hospital use

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|--|---|----------------|-------------------|---------------|--|--|--|
|  |   |                |                   |               |  |  | 1 x 4 mL vial)   |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial) SW  |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack) SW |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) SW  |
| <hr/>  |   |                |                   |               |  |  |  |
| <b>DOCETAXEL</b>   |   |                |                   |               |  |  |  |
| <b>Caution</b>   |   |                |                   |               |  |  |  |
| Pharmaceutical benefits containing docetaxel may have different concentrations.  |   |                |                   |               |  |  |  |
| <b>Authority required (STREAMLINED)</b>  |   |                |                   |               |  |  |  |
| <b>3888</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>Note</b>  |   |                |                   |               |  |  |  |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution. |   |                |                   |               |  |  |  |
| <b>Note</b>  |   |                |                   |               |  |  |  |
| The carcinoma can be considered inoperable for technical or organ preservation reasons.  |   |                |                   |               |  |  |  |
| <b>Note</b>  |   |                |                   |               |  |  |  |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. |   |                |                   |               |  |  |  |
| 5583W  | Injection   | 250 mg         | 5                 | ..            | *931.47  | 36.10  | DBL Docetaxel Concentrated Injection (docetaxel 160 mg/16 mL injection, 1 x 16 mL vial) HH                       |
|  |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) HH                          |
|  |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) HH                          |
|  |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) HX   |
|  |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) HX   |
|  |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) SZ  |
|  |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) SZ  |
|  |   |                |                   |               |  |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial) TA  |
|  |   |                |                   |               |  |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial) TA  |
|  |   |                |                   |               |  |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) TA  |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial) SW  |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack) SW |
|  |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) SW  |

**DOCETAXEL****Caution**

Pharmaceutical benefits containing docetaxel may have different concentrations.

**Authority required (STREAMLINED)****3892**

Adjuvant treatment of operable breast cancer in combination with cyclophosphamide

**Note**

Pharmaceutical benefits that have the form docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and pharmaceutical benefits that have the

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|-------|--|----------------|-------------------|---------------|--|--|--|----|
|       | form docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.   |                |                   |               |  |  |  |    |
|       | <b>Note</b>  |                |                   |               |  |  |  |    |
|       | A maximum of four cycles of treatment will be authorised under this restriction.   |                |                   |               |  |  |  |    |
|       | <b>Note</b>  |                |                   |               |  |  |  |    |
|       | 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. |                |                   |               |  |  |  |    |
| 5584X | Injection  | 250 mg         | 5                 | ..            | *931.47  | 36.10  | DBL Docetaxel Concentrated Injection<br>(docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)                   | HH |
|       |  |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                      | HH |
|       |  |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                      | HH |
|       |  |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)   | SZ |
|       |  |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)   | SZ |
|       |  |                |                   |               |  |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)   | TA |
|       |  |                |                   |               |  |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | TA |
|       |  |                |                   |               |  |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | TA |
|       |  |                |                   |               |  |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | SW |
|       |  |                |                   |               |  |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (& inert substance diluent [1 x 6 mL vial], 1 pack) | SW |
|       |  |                |                   |               |  |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | SW |

### DOCETAXEL

#### Caution

Pharmaceutical benefits containing docetaxel may have different concentrations.

#### Authority required (STREAMLINED)

**4078**

Locally advanced or metastatic non-small cell lung cancer

#### Authority required (STREAMLINED)

**4140**

Advanced metastatic ovarian cancer

#### **The Clinical criteria is:**

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

#### Authority required (STREAMLINED)

**4155**

Androgen independent (castration resistant) metastatic carcinoma of the prostate

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

The treatment must be used as first-line chemotherapy,

#### **AND the Clinical criteria is:**

The treatment must be administered in three weekly cycles,

#### **AND the Clinical criteria is:**

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

#### Note

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

#### Note

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

## Chemotherapy Items for Public Hospital use

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|---|---|----------------|-------------------|---------------|--|--|--|----|
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>4160</b>   |   |                |                   |               |  |  |  |    |
| Metastatic breast cancer  |   |                |                   |               |  |  |  |    |
| <b>Note</b>   |   |                |                   |               |  |  |  |    |
| 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. |   |                |                   |               |  |  |  |    |
| Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and 80 mg in 8 mL, docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) and docetaxel powder for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution. |   |                |                   |               |  |  |  |    |
| 5585Y   | Injection   | 250 mg         | 5                 | ..            | *931.47  | 36.10  | DBL Docetaxel Concentrated Injection<br>(docetaxel 160 mg/16 mL injection, 1 x 16 mL vial)                     | HH |
|   |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)                        | HH |
|   |   |                |                   |               |  |  | DBL Docetaxel Concentrated Injection<br>(docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)                        | HH |
|   |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)  | HX |
|   |   |                |                   |               |  |  | Docetaxel Ebewe (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)  | HX |
|   |   |                |                   |               |  |  | Docetaxel SUN (docetaxel 20 mg injection [1 x 20 mg vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack) | ZF |
|   |   |                |                   |               |  |  | Docetaxel SUN (docetaxel 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 x 4 mL vial], 1 pack) | ZF |
|   |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial)   | SZ |
|   |   |                |                   |               |  |  | Docetaxel Sandoz (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial)   | SZ |
|   |   |                |                   |               |  |  | Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial)   | TA |
|   |   |                |                   |               |  |  | Oncotaxel 20 (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | TA |
|   |   |                |                   |               |  |  | Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | TA |
|   |   |                |                   |               |  |  | Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial)   | SW |
|   |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&) inert substance diluent [1 x 6 mL vial], 1 pack)  | SW |
|   |   |                |                   |               |  |  | Taxotere (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial)   | SW |

### PACLITAXEL

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

**3890**

Locally advanced or metastatic non-small cell lung cancer

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

**3902**

Primary treatment of ovarian cancer in combination with a platinum compound

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

**3186**

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

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

**3917**

Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide

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

**3956**

Treatment of HER2 positive breast cancer in combination with trastuzumab

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

**3955**

## Chemotherapy Items for Public Hospital use

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|--|---|----------------|-------------------|---------------|--|--|--|----|
| Metastatic breast cancer   |   |                |                   |               |  |  |  |    |
| 4567J  | Injection   | 450 mg         | 3                 | ..            | *1179.20                                       | 36.10  | Anzatax (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)                    | HH |
|  |   |                |                   |               |  |  | Anzatax (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)                        | HH |
|  |   |                |                   |               |  |  | Anzatax (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                           | HH |
|  |   |                |                   |               |  |  | Anzatax (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)                        | HH |
|  |   |                |                   |               |  |  | GN-Paclitaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)              | YA |
|  |   |                |                   |               |  |  | GN-Paclitaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                     | YA |
|  |   |                |                   |               |  |  | GN-Paclitaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)                  | YA |
|  |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)         | TA |
|  |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)             | TA |
|  |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                | TA |
|  |   |                |                   |               |  |  | Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)             | TA |
|  |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)           | SZ |
|  |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)               | SZ |
|  |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)                 | SZ |
|  |   |                |                   |               |  |  | Paclitaxel Ebewe (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)               | SZ |
|  |   |                |                   |               |  |  | Paclitaxel Kabi (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)            | PK |
|  |   |                |                   |               |  |  | Paclitaxel Kabi (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                   | PK |
|  |   |                |                   |               |  |  | Paclitaxel Kabi (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)                | PK |
|  |   |                |                   |               |  |  | Paclitaxel Pfizer (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)          | PF |
|  |   |                |                   |               |  |  | Paclitaxel Pfizer (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                 | PF |
|  |   |                |                   |               |  |  | Paclitaxel Pfizer (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)              | PF |
|  |   |                |                   |               |  |  | Plaxel (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)                     | WQ |
|  |   |                |                   |               |  |  | Plaxel (paclitaxel 150 mg/25 mL injection, 1 x 25 mL vial)                         | WQ |
|  |   |                |                   |               |  |  | Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                            | WQ |
|  |   |                |                   |               |  |  | Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)                         | WQ |
|  |   |                |                   |               |  |  | Taxol (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial)                      | BQ |
|  |   |                |                   |               |  |  | Taxol (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial)                             | BQ |
|  |   |                |                   |               |  |  | Taxol (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial)                          | BQ |
| <b>PACLITAXEL NANOPARTICLE ALBUMIN BOUND</b>                             |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>                           |   |                |                   |               |  |  |  |    |
| <b>3955</b>  |   |                |                   |               |  |  |  |    |
| Metastatic breast cancer   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>                           |   |                |                   |               |  |  |  |    |
| <b>3956</b>  |   |                |                   |               |  |  |  |    |
| Treatment of HER2 positive breast cancer in combination with trastuzumab |   |                |                   |               |  |  |  |    |
| 4531L  | Injection   | 580 mg         | 5                 | ..            | *2449.52                                       | 36.10  | Abraxane (paclitaxel nanoparticle albumin bound 100 mg injection, 1 x 100 mg vial) | TS |

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|---|---|----------------|-------------------|---------------|--|--|--|----|
| <b>CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES</b>   |   |                |                   |               |  |  |  |    |
| <b><i>Anthracyclines and related substances</i></b>   |   |                |                   |               |  |  |  |    |
| <b>DOXORUBICIN</b>  |   |                |                   |               |  |  |  |    |
| 4361M   | Injection/intravenous                             | 135 mg         | 11                | ..            | *98.05   | 36.10  | Accord Doxorubicin (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                         | WQ |
|   |   |                |                   |               |  |  | Accord Doxorubicin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                    | WQ |
|   |   |                |                   |               |  |  | Adriamycin (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                            | PF |
|   |   |                |                   |               |  |  | Adriamycin Solution (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                      | PF |
|   |   |                |                   |               |  |  | Doxorubicin Ebewe (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                          | SZ |
|   |   |                |                   |               |  |  | Doxorubicin Ebewe (doxorubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial)                       | SZ |
|   |   |                |                   |               |  |  | Doxorubicin Ebewe (doxorubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                     | SZ |
|   |   |                |                   |               |  |  | Doxorubicin Ebewe (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                        | SZ |
|   |   |                |                   |               |  |  | Hospira Pty Limited (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                        | HH |
|   |   |                |                   |               |  |  | Hospira Pty Limited (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                      | HH |
| <b>DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL</b>  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3905</b>   |   |                |                   |               |  |  |  |    |
| Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen      |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3910</b>   |   |                |                   |               |  |  |  |    |
| Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3911</b>   |   |                |                   |               |  |  |  |    |
| Metastatic breast cancer, as monotherapy, where therapy with capecitabine and/or a taxane is contraindicated      |   |                |                   |               |  |  |  |    |
| 4360L   | Injection   | 100 mg         | 5                 | ..            | *3155.59                                       | 36.10  | Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)               | JC |
| 4364Q   | Injection   | 100 mg         | 5                 | ..            | *3007.24                                       | 36.10  | Caelyx (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)               | JC |
|   |   |                |                   |               |  |  | Caelyx (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)               | JC |
|   |   |                |                   |               |  |  | Lipodox (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)              | ZF |
|   |   |                |                   |               |  |  | Lipodox 50 (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)           | ZF |
| <b>EPIRUBICIN</b>   |   |                |                   |               |  |  |  |    |
| 4375G   | Injection/intravenous                             | 220 mg         | 5                 | ..            | *202.09  | 36.10  | DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) | HH |
|   |   |                |                   |               |  |  | Epiccord (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                                    | WQ |
|   |   |                |                   |               |  |  | Epiccord (epirubicin hydrochloride 20 mg/10 mL injection, 1 x 10 mL vial)                                  | WQ |
|   |   |                |                   |               |  |  | Epiccord (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial)                               | WQ |
|   |   |                |                   |               |  |  | Epiccord (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial)                                  | WQ |
|   |   |                |                   |               |  |  | Epirubicin Actavis 10 (epirubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial)                       | TA |
|   |   |                |                   |               |  |  | Epirubicin Actavis 100 (epirubicin hydrochloride 100 mg/5 mL injection, 1 x 5 mL vial)                     | TA |



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| Code  | Name, Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer  |    |
|---|---|----------------|-------------------|---------------|--|--|--|----|
|   |   |                |                   |               |  |  | Hospira Pty Limited (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial)            | HH |
|   |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial)    | PF |
|   |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial)    | PF |
| <b>CISPLATIN</b>  |   |                |                   |               |  |  |  |    |
| 4319H   | Injection   | 220 mg         | 14                | ..            | *77.94   | 36.10  | Cisplatin Ebewe (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)             | SZ |
|   |   |                |                   |               |  |  | Hospira Pty Limited (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)         | HH |
|   |   |                |                   |               |  |  | Hospira Pty Limited (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)            | HH |
|   |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial)    | PF |
|   |   |                |                   |               |  |  | Pfizer Australia Pty Ltd (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial)       | PF |
| <b>OXALIPLATIN</b>  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3930</b>   |   |                |                   |               |  |  |  |    |
| Adjuvant treatment of stage III (Dukes C) colon cancer following complete resection of the primary tumour used in combination with capecitabine   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3939</b>   |   |                |                   |               |  |  |  |    |
| 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  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3900</b>   |   |                |                   |               |  |  |  |    |
| Metastatic colorectal cancer in a patient with a WHO performance status of 2 or less, to be used in combination with capecitabine   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                |                   |               |  |  |  |    |
| <b>3901</b>   |   |                |                   |               |  |  |  |    |
| 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  |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>  |   |                |                   |               |  |  |  |    |
| 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. |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>  |   |                |                   |               |  |  |  |    |
| 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.   |   |                |                   |               |  |  |  |    |
| <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.  |   |                |                   |               |  |  |  |    |
| 4542C   | Injection   | 300 mg         | 11                | ..            | *277.52  | 36.10  | AS-Oxaliplatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)              | YA |
|   |   |                |                   |               |  |  | AS-Oxaliplatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)              | YA |
|   |   |                |                   |               |  |  | AS-Oxaliplatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)               | YA |
|   |   |                |                   |               |  |  | DBL Oxaliplatin Concentrate (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) | HH |
|   |   |                |                   |               |  |  | DBL Oxaliplatin Concentrate (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)  | HH |
|   |   |                |                   |               |  |  | Eloxatin (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)                    | SW |
|   |   |                |                   |               |  |  | Eloxatin (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)                    | SW |
|   |   |                |                   |               |  |  | Eloxatin (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)                     | SW |
|   |   |                |                   |               |  |  | Hospira Pty Limited (oxaliplatin 100 mg injection, 1 x 100 mg vial)              | HH |
|   |   |                |                   |               |  |  | Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial)                | HH |
|   |   |                |                   |               |  |  | Oxalliccord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)                 | WQ |
|   |   |                |                   |               |  |  | Oxalliccord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)                  | WQ |

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|------|---|----------------|-------------------|---------------|--|--|--|----|
|      |   |                |                   |               |  |  | x 10 mL vial)  |    |
|      |   |                |                   |               |  |  | Oxaliplatin Actavis (oxaliplatin 100 mg injection, 1 x 100 mg vial)    | TA |
|      |   |                |                   |               |  |  | Oxaliplatin Actavis (oxaliplatin 50 mg injection, 1 x 50 mg vial)      | TA |
|      |   |                |                   |               |  |  | Oxaliplatin Alphapharm (oxaliplatin 100 mg injection, 1 x 100 mg vial) | AF |
|      |   |                |                   |               |  |  | Oxaliplatin Alphapharm (oxaliplatin 50 mg injection, 1 x 50 mg vial)   | AF |
|      |   |                |                   |               |  |  | Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial)      | SZ |
|      |   |                |                   |               |  |  | Oxaliplatin Ebewe (oxaliplatin 50 mg injection, 1 x 50 mg vial)        | SZ |
|      |   |                |                   |               |  |  | Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)  | PK |
|      |   |                |                   |               |  |  | Oxaliplatin Kabi (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)   | PK |
|      |   |                |                   |               |  |  | Oxaliplatin SUN (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial)   | ZF |
|      |   |                |                   |               |  |  | Oxaliplatin SUN (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial)   | ZF |
|      |   |                |                   |               |  |  | Oxaliplatin SUN (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial)    | ZF |
|      |   |                |                   |               |  |  | Xalox (oxaliplatin 100 mg injection, 1 x 100 mg vial)                  | WQ |
|      |   |                |                   |               |  |  | Xalox (oxaliplatin 50 mg injection, 1 x 50 mg vial)                    | WQ |

### Monoclonal antibodies

#### BEVACIZUMAB

##### Authority required (STREAMLINED)

3894

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

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

##### Authority required (STREAMLINED)

3896

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

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

##### Note

Special Pricing Arrangements apply.

##### Note

Not for use as monotherapy.

|       |           |        |    |    |          |       |  |    |
|-------|-----------|--------|----|----|----------|-------|--|----|
| 4400N | Injection | 900 mg | 11 | .. | *3910.64 | 36.10 | Avastin (bevacizumab 100 mg/4 mL injection, 1 x 4 mL vial)   | RO |
|       |           |        |    |    |          |       | Avastin (bevacizumab 400 mg/16 mL injection, 1 x 16 mL vial) | RO |

#### CETUXIMAB

##### Authority required (STREAMLINED)

3919

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

##### Authority required (STREAMLINED)

3920

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

##### Note

No applications for repeats will be authorised.

|       |           |        |    |    |          |       |  |    |
|-------|-----------|--------|----|----|----------|-------|--|----|
| 4312Y | Injection | 880 mg | .. | .. | *3109.64 | 36.10 | Erbix (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial) | SG |
|-------|-----------|--------|----|----|----------|-------|--|----|

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|--|---|----------------|-------------------|---------------|--|--|--|----|
|  |   |                |                   |               |  |  | Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) | SG |
| <hr/>  |   |                |                   |               |  |  |  |    |
| <b>CETUXIMAB</b>   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>   |   |                |                   |               |  |  |  |    |
| <b>3921</b>  |   |                |                   |               |  |  |  |    |
| 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  |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |  |    |
| A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site for patients in whom radiotherapy is interrupted.   |   |                |                   |               |  |  |  |    |
| 4435K  | Injection   | 550 mg         | 5                 | ..            | *2086.64                                       | 36.10  | Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)   | SG |
|  |   |                |                   |               |  |  | Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) | SG |
| <hr/>  |   |                |                   |               |  |  |  |    |
| <b>CETUXIMAB</b>   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>   |   |                |                   |               |  |  |  |    |
| <b>3903</b>  |   |                |                   |               |  |  |  |    |
| 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                                  |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |  |    |
| Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.  |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |  |    |
| Special Pricing Arrangements apply.  |   |                |                   |               |  |  |  |    |
| 4436L  | Injection   | 880 mg         | ..                | ..            | *3109.64                                       | 36.10  | Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)   | SG |
|  |   |                |                   |               |  |  | Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) | SG |
| <hr/>  |   |                |                   |               |  |  |  |    |
| <b>CETUXIMAB</b>   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>   |   |                |                   |               |  |  |  |    |
| <b>3904</b>  |   |                |                   |               |  |  |  |    |
| 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 |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |  |    |
| Special Pricing Arrangements apply.  |   |                |                   |               |  |  |  |    |
| <b><u>Note</u></b>   |   |                |                   |               |  |  |  |    |
| Cetuximab is not PBS-subsidised for use in combination with bevacizumab or oxaliplatin based therapies.  |   |                |                   |               |  |  |  |    |
| 4731B  | Injection   | 550 mg         | 11                | ..            | *2086.64                                       | 36.10  | Erbitux (cetuximab 100 mg/20 mL injection, 1 x 20 mL vial)   | SG |
|  |   |                |                   |               |  |  | Erbitux (cetuximab 500 mg/100 mL injection, 1 x 100 mL vial) | SG |
| <hr/>  |   |                |                   |               |  |  |  |    |
| <b>RITUXIMAB</b>   |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>   |   |                |                   |               |  |  |  |    |
| <b>3912</b>  |   |                |                   |               |  |  |  |    |
| Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy  |   |                |                   |               |  |  |  |    |
| <b><u>Authority required (STREAMLINED)</u></b>   |   |                |                   |               |  |  |  |    |
| <b>3915</b>  |   |                |                   |               |  |  |  |    |
| Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy   |   |                |                   |               |  |  |  |    |
| 4613T  | Injection   | 800 mg         | 7                 | ..            | *3662.37                                       | 36.10  | Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) | RO |
|  |   |                |                   |               |  |  | Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)  | RO |

**RITUXIMAB****Authority required (STREAMLINED)**

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|-------|--|----------------|-------------------|---------------|--|--|--|----|
|       | <b>3908</b>  |                |                   |               |  |  |  |    |
|       | Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma   |                |                   |               |  |  |  |    |
|       | <b>Authority required (STREAMLINED)</b>  |                |                   |               |  |  |  |    |
|       | <b>3909</b>  |                |                   |               |  |  |  |    |
|       | Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma  |                |                   |               |  |  |  |    |
| 4614W | Injection  | 800 mg         | 3                 | ..            | *3662.37                                       | 36.10  | Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) | RO |
|       |  |                |                   |               |  |  | Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)  | RO |
| <hr/> |  |                |                   |               |  |  |  |    |
|       | <b>RITUXIMAB</b>   |                |                   |               |  |  |  |    |
|       | <b>Authority required (STREAMLINED)</b>  |                |                   |               |  |  |  |    |
|       | <b>3932</b>  |                |                   |               |  |  |  |    |
|       | CD20 positive, chronic lymphocytic leukaemia, in combination with fludarabine and cyclophosphamide   |                |                   |               |  |  |  |    |
|       | <b>Note</b>  |                |                   |               |  |  |  |    |
|       | Rituximab is not PBS-subsidised for use as monotherapy.  |                |                   |               |  |  |  |    |
| 4615X | Injection  | 1100 mg        | 5                 | ..            | *5020.50                                       | 36.10  | Mabthera (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) | RO |
|       |  |                |                   |               |  |  | Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial)  | RO |
|       | <b>TRASTUZUMAB</b>   |                |                   |               |  |  |  |    |
|       | <b>Authority required</b>  |                |                   |               |  |  |  |    |
|       | Locally advanced HER2 positive breast cancer   |                |                   |               |  |  |  |    |
|       | Treatment Phase: Initial treatment (weekly regimen)  |                |                   |               |  |  |  |    |
|       | <b>The Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | Patient must commence treatment concurrently with neoadjuvant chemotherapy,  |                |                   |               |  |  |  |    |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,   |                |                   |               |  |  |  |    |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.   |                |                   |               |  |  |  |    |
|       | HER2 positivity must be demonstrated by in situ hybridisation (ISH).   |                |                   |               |  |  |  |    |
|       | Authority applications for initial treatment must be made in writing and must include:   |                |                   |               |  |  |  |    |
|       | (a) a completed authority prescription form; and   |                |                   |               |  |  |  |    |
|       | (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:  |                |                   |               |  |  |  |    |
|       | (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and                               |                |                   |               |  |  |  |    |
|       | (ii) a copy of the signed patient acknowledgement form.  |                |                   |               |  |  |  |    |
|       | Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment. |                |                   |               |  |  |  |    |
|       | For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 4 mg per kg.      |                |                   |               |  |  |  |    |
|       | <b>Authority required</b>  |                |                   |               |  |  |  |    |
|       | Early HER2 positive breast cancer  |                |                   |               |  |  |  |    |
|       | Treatment Phase: Initial treatment (weekly regimen)  |                |                   |               |  |  |  |    |
|       | <b>The Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | Patient must commence treatment concurrently with adjuvant chemotherapy,   |                |                   |               |  |  |  |    |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | Patient must have undergone surgery,   |                |                   |               |  |  |  |    |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure,   |                |                   |               |  |  |  |    |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |  |    |
|       | Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.   |                |                   |               |  |  |  |    |
|       | HER2 positivity must be demonstrated by in situ hybridisation (ISH).   |                |                   |               |  |  |  |    |
|       | Authority applications for initial treatment must be made in writing and must include:   |                |                   |               |  |  |  |    |

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|-------|--|----------------|-------------------|---------------|--|--|---|
|       | <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:</p> <p>(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and</p> <p>(ii) a copy of the signed patient acknowledgement form.</p> <p>Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.</p> <p>For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 4 mg per kg.</p> <p><b>Note</b><br/>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br/>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a><br/>Applications for authority to prescribe should be forwarded to:<br/>Department of Human Services<br/>Prior Written Approval of Complex Drugs<br/>Reply Paid 9826<br/>GPO Box 9826<br/>HOBART TAS 7001</p> |                |                   |               |  |  |   |
| 4632T | Injection  | 500 mg         | ..                | ..            | *3543.33                                       | 36.10  | <p>Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) RO</p> <p>Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) RO</p> |

### TRASTUZUMAB

#### **Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 2 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### **Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

For a patient on the weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 2 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority

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|--|---|----------------|-------------------|---------------|--|--|--|----------|
| approval will be granted for a new loading dose.   |   |                |                   |               |  |  |  |          |
| <b>Note</b><br>Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |   |                |                   |               |  |  |  |          |
| <b>Note</b><br>Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).   |   |                |                   |               |  |  |  |          |
| <b>Note</b><br>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).<br>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a><br>Applications for authority to prescribe should be forwarded to:<br>Department of Human Services<br>Prior Written Approval of Complex Drugs<br>Reply Paid 9826<br>GPO Box 9826<br>HOBART TAS 7001 |   |                |                   |               |  |  |  |          |
| 4639E  | Injection   | 250 mg         | 9                 | ..            | *1895.01                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial)<br>Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) | RO<br>RO |

### TRASTUZUMAB

#### **Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

#### **The Clinical criteria is:**

Patient must commence treatment concurrently with neoadjuvant chemotherapy,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:
  - (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
  - (ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 8 mg per kg.

#### **Authority required**

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

#### **The Clinical criteria is:**

Patient must commence treatment concurrently with adjuvant chemotherapy,

#### **AND the Clinical criteria is:**

Patient must have undergone surgery,

#### **AND the Clinical criteria is:**

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

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer  |          |
|---|---|----------------|-------------------|---------------|--|--|--|----------|
| <b>AND the Clinical criteria is:</b>  |   |                |                   |               |  |  |  |          |
| Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.  |   |                |                   |               |  |  |  |          |
| HER2 positivity must be demonstrated by in situ hybridisation (ISH).  |   |                |                   |               |  |  |  |          |
| Authority applications for initial treatment must be made in writing and must include:  |   |                |                   |               |  |  |  |          |
| (a) a completed authority prescription form; and  |   |                |                   |               |  |  |  |          |
| (b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:   |   |                |                   |               |  |  |  |          |
| (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and  |   |                |                   |               |  |  |  |          |
| (ii) a copy of the signed patient acknowledgement form.   |   |                |                   |               |  |  |  |          |
| Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.  |   |                |                   |               |  |  |  |          |
| For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a single loading dose of 8 mg per kg.   |   |                |                   |               |  |  |  |          |
| <b>Note</b>   |   |                |                   |               |  |  |  |          |
| Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |   |                |                   |               |  |  |  |          |
| Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> |   |                |                   |               |  |  |  |          |
| Applications for authority to prescribe should be forwarded to:   |   |                |                   |               |  |  |  |          |
| Department of Human Services  |   |                |                   |               |  |  |  |          |
| Prior Written Approval of Complex Drugs   |   |                |                   |               |  |  |  |          |
| Reply Paid 9826   |   |                |                   |               |  |  |  |          |
| GPO Box 9826  |   |                |                   |               |  |  |  |          |
| HOBART TAS 7001   |   |                |                   |               |  |  |  |          |
| 4650R   | Injection   | 1000 mg        | ..                | ..            | *7046.00                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial)<br>Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial) | RO<br>RO |

### TRASTUZUMAB

#### **Authority required**

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 6 mg per kg.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

#### **Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration   | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                               |    |
|-------|---|----------------|-------------------|---------------|--|--|---|----|
|       | Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.   |                |                   |               |  |  |   |    |
|       | For a patient on the 3 weekly regimen the medical practitioner should request sufficient quantity based on the weight of the patient to provide for a dose of 6 mg per kg.  |                |                   |               |  |  |   |    |
|       | Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.  |                |                   |               |  |  |   |    |
|       | <b>Note</b>   |                |                   |               |  |  |   |    |
|       | Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |                |                   |               |  |  |   |    |
|       | <b>Note</b>   |                |                   |               |  |  |   |    |
|       | Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).   |                |                   |               |  |  |   |    |
|       | <b>Note</b>   |                |                   |               |  |  |   |    |
|       | Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |                |                   |               |  |  |   |    |
|       | Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> |                |                   |               |  |  |   |    |
|       | Applications for authority to prescribe should be forwarded to:   |                |                   |               |  |  |   |    |
|       | Department of Human Services  |                |                   |               |  |  |   |    |
|       | Prior Written Approval of Complex Drugs   |                |                   |               |  |  |   |    |
|       | Reply Paid 9826   |                |                   |               |  |  |   |    |
|       | GPO Box 9826  |                |                   |               |  |  |   |    |
|       | HOBART TAS 7001   |                |                   |               |  |  |   |    |
| 4703M | Injection   | 750 mg         | 3                 | ..            | *5191.65                                       | 36.10  | Herceptin (trastuzumab 150 mg injection, 1 x 150 mg vial) | RO |
|       |   |                |                   |               |  |  | Herceptin (trastuzumab 60 mg injection, 1 x 60 mg vial)   | RO |

### Other antineoplastic agents

#### ARSENIC

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

**3891**

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

|       |           |       |    |    |         |       |   |    |
|-------|-----------|-------|----|----|---------|-------|---|----|
| 4371C | Injection | 18 mg | 89 | .. | *842.30 | 36.10 | Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) | PL |
|-------|-----------|-------|----|----|---------|-------|---|----|

#### BORTEZOMIB

##### **Authority required**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

##### **The Clinical criteria is:**

Patient must be newly diagnosed,

##### **AND the Clinical criteria is:**

Patient must be ineligible for high dose chemotherapy,

##### **AND the Clinical criteria is:**

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

##### **AND the Clinical criteria is:**

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

##### **AND the Clinical criteria is:**

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

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

(1) a completed authority prescription form; and

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

(3) a signed patient acknowledgement.

##### **Authority required**

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration   | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                           |
|-------|---|----------------|-------------------|---------------|--|--|---|
|       | Symptomatic multiple myeloma  |                |                   |               |  |  |   |
|       | Treatment Phase: Initial PBS-subsidised treatment   |                |                   |               |  |  |   |
|       | <b>The Clinical criteria is:</b>  |                |                   |               |  |  |   |
|       | Patient must be newly diagnosed,  |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>  |                |                   |               |  |  |   |
|       | Patient must have severe acute renal failure,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>  |                |                   |               |  |  |   |
|       | Patient must require dialysis; OR   |                |                   |               |  |  |   |
|       | Patient must be at high risk of requiring dialysis in the opinion of a nephrologist,  |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>  |                |                   |               |  |  |   |
|       | The treatment must be in combination with a corticosteroid and/or cyclophosphamide,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>  |                |                   |               |  |  |   |
|       | Patient must not be receiving PBS-subsidised thalidomide or lenalidomide,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>  |                |                   |               |  |  |   |
|       | Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.  |                |                   |               |  |  |   |
|       | The authority application must be made in writing and must include:   |                |                   |               |  |  |   |
|       | (1) a completed authority prescription form; and  |                |                   |               |  |  |   |
|       | (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response; and |                |                   |               |  |  |   |
|       | (3) a signed patient acknowledgement.   |                |                   |               |  |  |   |
|       | Disease activity parameters include current diagnostic reports of at least one of the following:  |                |                   |               |  |  |   |
|       | (a) the level of serum monoclonal protein; or   |                |                   |               |  |  |   |
|       | (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or  |                |                   |               |  |  |   |
|       | (c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or   |                |                   |               |  |  |   |
|       | (d) bone marrow aspirate or trephine; or  |                |                   |               |  |  |   |
|       | (e) if present, the size and location of lytic bone lesions (not including compression fractures); or   |                |                   |               |  |  |   |
|       | (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or   |                |                   |               |  |  |   |
|       | (g) if present, the level of hypercalcaemia, corrected for albumin concentration.   |                |                   |               |  |  |   |
|       | As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients.   |                |                   |               |  |  |   |
|       | Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided.   |                |                   |               |  |  |   |
|       | Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.   |                |                   |               |  |  |   |
|       | <b>Note</b>   |                |                   |               |  |  |   |
|       | Patients who have initiated treatment with thalidomide within the last month do not have to experience failure after a trial of at least 4 weeks of thalidomide or to have failed to achieve at least a minimal response after at least 8 weeks of thalidomide treatment.   |                |                   |               |  |  |   |
|       | <b>Note</b>   |                |                   |               |  |  |   |
|       | Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |                |                   |               |  |  |   |
|       | Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>   |                |                   |               |  |  |   |
|       | Applications for authority to prescribe should be forwarded to:   |                |                   |               |  |  |   |
|       | Department of Human Services  |                |                   |               |  |  |   |
|       | Prior Written Approval of Complex Drugs   |                |                   |               |  |  |   |
|       | Reply Paid 9826   |                |                   |               |  |  |   |
|       | GPO Box 9826  |                |                   |               |  |  |   |
|       | HOBART TAS 7001   |                |                   |               |  |  |   |
|       | <b>Note</b>   |                |                   |               |  |  |   |
|       | Special Pricing Arrangements apply.   |                |                   |               |  |  |   |
| 4403R | Injection   | 3000 mcg       | 31                | ..            | *1509.77                                       | 36.10  | Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) JC |

## Chemotherapy Items for Public Hospital use

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

### **BORTEZOMIB**

#### **Authority required**

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

#### **Note**

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

#### **Authority required**

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

#### **The Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form, which includes a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are not being used to monitor disease activity, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration   | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                           |
|-------|---|----------------|-------------------|---------------|--|--|---|
|       | (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.  |                |                   |               |  |  |   |
|       | Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application.   |                |                   |               |  |  |   |
|       | <b>Note</b>   |                |                   |               |  |  |   |
|       | Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  |                |                   |               |  |  |   |
|       | Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> |                |                   |               |  |  |   |
|       | Applications for authority to prescribe should be forwarded to:   |                |                   |               |  |  |   |
|       | Department of Human Services  |                |                   |               |  |  |   |
|       | Prior Written Approval of Complex Drugs   |                |                   |               |  |  |   |
|       | Reply Paid 9826   |                |                   |               |  |  |   |
|       | GPO Box 9826  |                |                   |               |  |  |   |
|       | HOBART TAS 7001   |                |                   |               |  |  |   |
|       | <b>Note</b>   |                |                   |               |  |  |   |
|       | Authority applications for continuing treatment may be faxed to the Department of Human Services on 1300 154 190 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.        |                |                   |               |  |  |   |
|       | <b>Note</b>   |                |                   |               |  |  |   |
|       | Special Pricing Arrangements apply.   |                |                   |               |  |  |   |
| 4429D | Injection   | 3000 mcg       | 19                | ..            | *1509.77                                       | 36.10  | Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) JC |

### **BORTEZOMIB**

#### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The condition must be confirmed by a histological diagnosis,

#### **AND the Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

#### **AND the Clinical criteria is:**

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

#### **AND the Clinical criteria is:**

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

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
  - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
  - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
  - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
  - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
  - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
  - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).
- Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

## Chemotherapy Items for Public Hospital use

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

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

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

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) duration of thalidomide and daily dose prescribed; and
- (4) a signed patient acknowledgment.

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

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

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

### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

## Chemotherapy Items for Public Hospital use

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

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
- (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

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

### **Note**

Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

### **Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

### **Note**

Special Pricing Arrangements apply.

|       |           |          |    |    |          |       |  |    |
|-------|-----------|----------|----|----|----------|-------|--|----|
| 4706Q | Injection | 3000 mcg | 15 | .. | *1754.64 | 36.10 | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) | JC |
|-------|-----------|----------|----|----|----------|-------|--|----|

## **BORTEZOMIB**

### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration   | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                               |
|-------|---|----------------|-------------------|---------------|--|--|---|
|       | <p>(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and</p> <p>(3) diagnostic reports demonstrating the patient has achieved at least a partial response.</p> <p>If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).</p> <p>If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.</p> <p>If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.</p> <p>If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(a) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or</p> <p>(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.</p> <p>Diagnostic reports must be no more than one month old at the time of application.</p> <p>Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib.</p> <p>Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.</p> <p><b>Note</b><br/>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services<br/>Prior Written Approval of Complex Drugs<br/>Reply Paid 9826<br/>GPO Box 9826<br/>HOBART TAS 7001</p> <p><b>Note</b><br/>Special Pricing Arrangements apply.</p> |                |                   |               |  |  |   |
| 4712B | Injection   | 3000 mcg       | 11                | ..            | *1754.64                                       | 36.10  | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC |

### **BORTEZOMIB**

#### **Authority required**

Multiple myeloma

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

#### **The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

#### **AND the Clinical criteria is:**

Patient must have progressive disease,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

Patient must not be receiving concomitant PBS-subsidised lenalidomide,

#### **AND the Clinical criteria is:**

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

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

## Chemotherapy Items for Public Hospital use

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

- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
- (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application - Supporting Information Form which includes details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously provided; and
- (4) a signed patient acknowledgment.

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

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

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

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

### **Authority required**

Multiple myeloma

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

### **The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

### **AND the Clinical criteria is:**

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

### **AND the Clinical criteria is:**

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

### **AND the Clinical criteria is:**

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

## Chemotherapy Items for Public Hospital use

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

**AND the Clinical criteria is:**

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

**AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and
- (3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

- (a) at least a 50% reduction in bone marrow plasma cells; or
- (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
- (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

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

**Note**

Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

|       |           |          |    |    |          |       |  |    |
|-------|-----------|----------|----|----|----------|-------|--|----|
| 4713C | Injection | 3000 mcg | 15 | .. | *1754.64 | 36.10 | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) | JC |
|-------|-----------|----------|----|----|----------|-------|--|----|

**BORTEZOMIB**

**Authority required**

Multiple myeloma

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

**The Clinical criteria is:**

The treatment must be as monotherapy; OR

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

**AND the Clinical criteria is:**

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

**AND the Clinical criteria is:**

## Chemotherapy Items for Public Hospital use

| Code  | Name, Restriction,<br>Manner of<br>Administration  | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer                               |
|-------|--|----------------|-------------------|---------------|--|--|---|
|       | Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must not have received 2 treatment cycles after first achieving a confirmed complete response,   |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must not have a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles,  |                |                   |               |  |  |   |
|       | <b>AND the Clinical criteria is:</b>   |                |                   |               |  |  |   |
|       | Patient must not receive more than 3 cycles of bortezomib under this restriction.  |                |                   |               |  |  |   |
|       | The authority application must be made in writing and must include:  |                |                   |               |  |  |   |
|       | (1) a completed authority prescription form; and   |                |                   |               |  |  |   |
|       | (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and   |                |                   |               |  |  |   |
|       | (3) diagnostic reports demonstrating the patient has achieved at least a partial response.   |                |                   |               |  |  |   |
|       | If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).   |                |                   |               |  |  |   |
|       | If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. |                |                   |               |  |  |   |
|       | If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.                                   |                |                   |               |  |  |   |
|       | If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:  |                |                   |               |  |  |   |
|       | (a) at least a 50% reduction in bone marrow plasma cells; or   |                |                   |               |  |  |   |
|       | (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or  |                |                   |               |  |  |   |
|       | (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or   |                |                   |               |  |  |   |
|       | (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.   |                |                   |               |  |  |   |
|       | Diagnostic reports must be no more than one month old at the time of application.  |                |                   |               |  |  |   |
|       | Where a response assessment is not submitted prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib.   |                |                   |               |  |  |   |
|       | Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.  |                |                   |               |  |  |   |
|       | <b>Note</b>  |                |                   |               |  |  |   |
|       | Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).   |                |                   |               |  |  |   |
|       | Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>  |                |                   |               |  |  |   |
|       | Applications for authority to prescribe should be forwarded to:  |                |                   |               |  |  |   |
|       | Department of Human Services   |                |                   |               |  |  |   |
|       | Prior Written Approval of Complex Drugs  |                |                   |               |  |  |   |
|       | Reply Paid 9826  |                |                   |               |  |  |   |
|       | GPO Box 9826   |                |                   |               |  |  |   |
|       | HOBART TAS 7001  |                |                   |               |  |  |   |
|       | <b>Note</b>  |                |                   |               |  |  |   |
|       | Special Pricing Arrangements apply.  |                |                   |               |  |  |   |
| 4725Q | Injection  | 3000 mcg       | 11                | ..            | *1754.64                                       | 36.10  | Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) JC |

### **BORTEZOMIB**

#### **Authority required**

Symptomatic multiple myeloma

#### **The Clinical criteria is:**

Patient must be newly diagnosed,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

## Chemotherapy Items for Public Hospital use

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

The treatment must be in combination with chemotherapy,

**AND the Clinical criteria is:**

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

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma; and
- (3) a signed patient acknowledgement.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
 Prior Written Approval of Complex Drugs  
 Reply Paid 9826  
 GPO Box 9826  
 HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

|       |           |          |    |    |          |       |  |    |
|-------|-----------|----------|----|----|----------|-------|--|----|
| 4732C | Injection | 3000 mcg | 15 | .. | *1509.77 | 36.10 | Velcade (bortezomib 1 mg injection, 1 x 1 mg vial) | JC |
|-------|-----------|----------|----|----|----------|-------|--|----|

**IRINOTECAN**

**Authority required (STREAMLINED)**

**3184**

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

**Note**

In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.

|       |           |        |    |    |         |       |   |    |
|-------|-----------|--------|----|----|---------|-------|---|----|
| 4451G | Injection | 800 mg | 11 | .. | *344.02 | 36.10 | Camptosar (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)              | PF |
|       |           |        |    |    |         |       | Hospira Pty Limited (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)      | HH |
|       |           |        |    |    |         |       | Hospira Pty Limited (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)       | HH |
|       |           |        |    |    |         |       | Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)    | HH |
|       |           |        |    |    |         |       | Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)               | WQ |
|       |           |        |    |    |         |       | Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)                | WQ |
|       |           |        |    |    |         |       | Irinotecan Actavis (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)       | TA |
|       |           |        |    |    |         |       | Irinotecan Actavis (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)        | TA |
|       |           |        |    |    |         |       | Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) | TA |
|       |           |        |    |    |         |       | Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)    | AF |
|       |           |        |    |    |         |       | Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)     | AF |
|       |           |        |    |    |         |       | Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)     | AF |

## Chemotherapy Items for Public Hospital use

| Code | Name, Restriction,<br>Manner of<br>Administration | Max.<br>Amount | No.<br>of<br>Rpts | Premium<br>\$ | Dispensed<br>Price for<br>Max.<br>Amount<br>\$ | Maximum<br>Recordable<br>Value for<br>Safety Net<br>\$ | Brand Name and Manufacturer  |    |
|------|---|----------------|-------------------|---------------|--|--|--|----|
|      |   |                |                   |               |  |  | hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)                                 |    |
|      |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)      | SZ |
|      |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial)    | SZ |
|      |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)       | SZ |
|      |   |                |                   |               |  |  | Irinotecan Ebewe (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)    | SZ |
|      |   |                |                   |               |  |  | Irinotecan Kabi (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)       | PK |
|      |   |                |                   |               |  |  | Irinotecan Kabi (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)        | PK |
|      |   |                |                   |               |  |  | Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) | OE |
|      |   |                |                   |               |  |  | Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)  | OE |
|      |   |                |                   |               |  |  | Tecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial)                 | WQ |
|      |   |                |                   |               |  |  | Tecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial)                  | WQ |
|      |   |                |                   |               |  |  | Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial)               | WQ |

### TOPOTECAN

#### Authority required (STREAMLINED)

3186

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

|       |           |          |    |    |         |       |   |    |
|-------|-----------|----------|----|----|---------|-------|---|----|
| 4617B | Injection | 3500 mcg | 17 | .. | *371.04 | 36.10 | Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials)       | GK |
|       |           |          |    |    |         |       | Topotecan Agila (topotecan 4 mg injection, 1 x 4 mg vial) | YA |
|       |           |          |    |    |         |       | Topotecan Kabi (topotecan 4 mg injection, 5 x 4 mg vials) | PK |



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

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

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

## ALIMENTARY TRACT AND METABOLISM

### ANTIEMETICS AND ANTINAUSEANTS

#### ANTIEMETICS AND ANTINAUSEANTS

##### *Serotonin (5HT3) antagonists*

##### GRANISETRON

##### Restricted benefit

Nausea and vomiting

##### The Clinical criteria is:

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

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

|       |   |   |    |    |        |       |                               |    |
|-------|---|---|----|----|--------|-------|-------------------------------|----|
| 5898K | granisetron 2 mg tablet, 1                        | 2 | .. | .. | *44.44 | 36.10 | Kytril                        | RO |
| 5899L | granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule | 1 | .. | .. | 25.42  | 26.53 | <sup>a</sup> Granisetron Kabi | PK |
|       |   |   |    |    |        |       | <sup>a</sup> Kytril           | RO |

##### ONDANSETRON

##### Restricted benefit

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

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

|       |   |   |    |    |       |       |                                 |    |
|-------|---|---|----|----|-------|-------|---------------------------------|----|
| 5848T | ondansetron 4 mg/5 mL oral liquid, 50 mL          | 1 | .. | .. | 80.78 | 36.10 | Zofran syrup 50 mL              | GK |
| 5967C | ondansetron 4 mg tablet, 4                        | 4 | .. | .. | 16.17 | 17.28 | <sup>a</sup> APO-Ondansetron    | TX |
|       |   |   |    |    |       |       | <sup>a</sup> Ondansetron-DRLA   | RZ |
|       |   |   |    |    |       |       | <sup>a</sup> Ondaz              | SZ |
|       |   |   |    |    |       |       | <sup>a</sup> Onsetron 4         | ZP |
|       |   |   |    |    |       |       | <sup>a</sup> Zofran             | GK |
| 5968D | ondansetron 8 mg tablet, 4                        | 4 | .. | .. | 25.33 | 26.44 | <sup>a</sup> APO-Ondansetron    | TX |
|       |   |   |    |    |       |       | <sup>a</sup> Ondansetron-DRLA   | RZ |
|       |   |   |    |    |       |       | <sup>a</sup> Ondaz              | SZ |
|       |   |   |    |    |       |       | <sup>a</sup> Onsetron 8         | ZP |
|       |   |   |    |    |       |       | <sup>a</sup> Zofran             | GK |
| 5971G | ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule | 1 | .. | .. | 1.93  | 5.50  | <sup>a</sup> Ondansetron        | AF |
|       |   |   |    |    |       |       | Alphapharm                      |    |
|       |   |   |    |    |       |       | <sup>a</sup> Ondansetron-Claris | AE |
|       |   |   |    |    |       |       | <sup>a</sup> Ondaz              | SZ |
|       |   |   |    |    |       |       | <sup>a</sup> Onsetron           | ZP |
|       |   |   |    |    |       |       | <sup>a</sup> Zofran             | GK |
| 5972H | ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule | 1 | .. | .. | 3.06  | 5.50  | <sup>a</sup> Ondansetron        | AF |
|       |   |   |    |    |       |       | Alphapharm                      |    |
|       |   |   |    |    |       |       | <sup>a</sup> Ondansetron-Claris | AE |
|       |   |   |    |    |       |       | <sup>a</sup> Ondaz              | SZ |
|       |   |   |    |    |       |       | <sup>a</sup> Onsetron           | ZP |
|       |   |   |    |    |       |       | <sup>a</sup> Zofran             | GK |

##### ONDANSETRON

##### Restricted benefit

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

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

##### Note

Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution.

|       |                            |   |    |    |       |       |                                   |    |
|-------|----------------------------|---|----|----|-------|-------|-----------------------------------|----|
| 5857G | ONDANSETRON Tablet (orally | 4 | .. | .. | 16.17 | 17.28 | <sup>a</sup> Ondansetron ODT-DRLA | RZ |
|-------|----------------------------|---|----|----|-------|-------|-----------------------------------|----|

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

| Code  | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium \$ | Dispensed Price for Max. Qty \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer                   |                |
|-------|--|------------------|-------------|------------|---------------------------------|--|---|----------------|
| 5969E | ondansetron 4 mg wafer, 4<br>disintegrating) 4 mg, 4 | 4                | ..          | ..         | 16.17                           | 17.28                                      | Onsetron ODT 4<br>Ondaz Zydis<br>Zofran Zydis | WQ<br>SZ<br>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 | ONDANSETRON Tablet (orally disintegrating) 8 mg, 4 | 4 | .. | .. | 25.33 | 25.33 | Ondansetron ODT-DRLA                          | RZ             |
| 5970F | ondansetron 8 mg wafer, 4                          | 4 | .. | .. | 25.33 | 25.33 | Onsetron ODT 8<br>Ondaz Zydis<br>Zofran Zydis | WQ<br>SZ<br>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 | palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial | 1 | .. | .. | 34.36 | 35.47 | Aloxi | TS |
|-------|--|---|----|----|-------|-------|-------|----|

### TROPISETRON

#### **Restricted benefit**

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

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

|       |   |   |    |    |       |       |         |    |
|-------|---|---|----|----|-------|-------|---------|----|
| 5986C | tropisetron 5 mg capsule, 2                       | 2 | .. | .. | 37.02 | 36.10 | Navoban | NV |
| 5987D | tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule | 1 | .. | .. | 18.50 | 18.50 | Navoban | NV |

### **Other antiemetics**

#### APREPITANT

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

##### **3619**

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

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

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

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

##### **3620**

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

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

| Code  | Name, Restriction, Manner of Administration and Form                                  | Max. Qty (Packs) | No. of Rpts | Premium \$ | Dispensed Price for Max. Qty \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer |
|---|---|------------------|-------------|------------|---------------------------------|--|-----------------------------|
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                  |             |            |                                 |  |                             |
| <b>3621</b>   |   |                  |             |            |                                 |  |                             |
| Management of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, in combination with a 5HT3 antagonist and dexamethasone on day 1, where the patient has had a prior episode of chemotherapy induced nausea or vomiting where any 1 of the following intravenous chemotherapy agents is to be administered: |   |                  |             |            |                                 |  |                             |
| (a) arsenic trioxide;   |   |                  |             |            |                                 |  |                             |
| (b) azacitidine;  |   |                  |             |            |                                 |  |                             |
| (c) carboplatin;  |   |                  |             |            |                                 |  |                             |
| (d) cyclophosphamide at a dose of less than 1500 mg per square metre per day;   |   |                  |             |            |                                 |  |                             |
| (e) cytarabine at a dose of greater than 1 g per square metre per day;  |   |                  |             |            |                                 |  |                             |
| (f) dactinomycin;   |   |                  |             |            |                                 |  |                             |
| (g) daunorubicin;   |   |                  |             |            |                                 |  |                             |
| (h) doxorubicin;  |   |                  |             |            |                                 |  |                             |
| (i) epirubicin;   |   |                  |             |            |                                 |  |                             |
| (j) fotemustine;  |   |                  |             |            |                                 |  |                             |
| (k) idarubicin;   |   |                  |             |            |                                 |  |                             |
| (l) ifosfamide;   |   |                  |             |            |                                 |  |                             |
| (m) irinotecan;   |   |                  |             |            |                                 |  |                             |
| (n) melphalan;  |   |                  |             |            |                                 |  |                             |
| (o) methotrexate at a dose of 250 mg to 1 g per square metre;   |   |                  |             |            |                                 |  |                             |
| (p) oxaliplatin;  |   |                  |             |            |                                 |  |                             |
| (q) raltitrexed.  |   |                  |             |            |                                 |  |                             |
| No more than one pack containing 1 x 125 mg capsule and 2 x 80 mg capsules will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle  |   |                  |             |            |                                 |  |                             |
| <b><u>Note</u></b>  |   |                  |             |            |                                 |  |                             |
| Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.   |   |                  |             |            |                                 |  |                             |
| <b><u>Note</u></b>  |   |                  |             |            |                                 |  |                             |
| No applications for increased maximum quantities and/or repeats will be authorised.   |   |                  |             |            |                                 |  |                             |
| 5888X   | aprepitant 125 mg capsule [1 capsule]<br>(&) aprepitant 80 mg capsule [2 capsules], 3 | #1               | 5           | ..         | 112.01                          | 36.10                                      | Emend MK                    |

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

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

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## IMMUNOSTIMULANTS

### IMMUNOSTIMULANTS

#### *Interferons*

#### INTERFERON ALFA-2A

##### **Caution**

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

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

**3180**

Hairy cell leukaemia

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

**3899**

Myeloproliferative disease with excessive thrombocytosis

|       |   |    |   |    |         |       |           |    |
|-------|---|----|---|----|---------|-------|-----------|----|
| 5945X | interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 15 | 4 | .. | *447.00 | 36.10 | Roferon-A | RO |
|-------|---|----|---|----|---------|-------|-----------|----|

#### INTERFERON ALFA-2A

##### **Caution**

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

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

**3895**

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

|       |   |    |   |    |         |       |           |    |
|-------|---|----|---|----|---------|-------|-----------|----|
| 5946Y | interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe   | 15 | 5 | .. | *447.00 | 36.10 | Roferon-A | RO |
| 5947B | interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5  | 5 | .. | *223.50 | 36.10 | Roferon-A | RO |
| 5948C | interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe   | 5  | 5 | .. | *297.90 | 36.10 | Roferon-A | RO |
| 5949D | interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe   | 5  | 5 | .. | *446.90 | 36.10 | Roferon-A | RO |

#### INTERFERON ALFA-2A

##### **Caution**

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

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

**3899**

Myeloproliferative disease with excessive thrombocytosis

|       |   |   |   |    |         |       |           |    |
|-------|---|---|---|----|---------|-------|-----------|----|
| 5996N | interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe | 5 | 4 | .. | *223.50 | 36.10 | Roferon-A | RO |
| 5997P | interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe   | 5 | 4 | .. | *297.90 | 36.10 | Roferon-A | RO |
| 5998Q | interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe   | 5 | 4 | .. | *446.90 | 36.10 | Roferon-A | RO |

#### INTERFERON ALFA-2B

##### **Caution**

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

| Code  | Name, Restriction, Manner of Administration and Form  | Max. Qty (Packs) | No. of Rpts | Premium \$ | Dispensed Price for Max. Qty \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer |    |
|---|---|------------------|-------------|------------|---------------------------------|--|-----------------------------|----|
| Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. |   |                  |             |            |                                 |  |                             |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                  |             |            |                                 |  |                             |    |
| <b>3180</b>   |   |                  |             |            |                                 |  |                             |    |
| Hairy cell leukaemia  |   |                  |             |            |                                 |  |                             |    |
| 5893E   | interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge  | 3                | 4           | ..         | *536.22                         | 36.10                                      | Intron A Redipen            | MK |
| <b>INTERFERON ALFA-2B</b>   |   |                  |             |            |                                 |  |                             |    |
| <b><u>Caution</u></b>   |   |                  |             |            |                                 |  |                             |    |
| Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. |   |                  |             |            |                                 |  |                             |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                  |             |            |                                 |  |                             |    |
| <b>3898</b>   |   |                  |             |            |                                 |  |                             |    |
| Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy  |   |                  |             |            |                                 |  |                             |    |
| <b><u>Authority required (STREAMLINED)</u></b>  |   |                  |             |            |                                 |  |                             |    |
| <b>3895</b>   |   |                  |             |            |                                 |  |                             |    |
| Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy  |   |                  |             |            |                                 |  |                             |    |
| 5953H   | interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge  | 3                | 5           | ..         | *536.22                         | 36.10                                      | Intron A Redipen            | MK |
| 5956L   | interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge  | 3                | 5           | ..         | *893.70                         | 36.10                                      | Intron A Redipen            | MK |
| <b><i>Other immunostimulants</i></b>  |   |                  |             |            |                                 |  |                             |    |
| <b>BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN</b>  |   |                  |             |            |                                 |  |                             |    |
| <b><u>Restricted benefit</u></b>  |   |                  |             |            |                                 |  |                             |    |
| Treatment of carcinoma in situ of the urinary bladder   |   |                  |             |            |                                 |  |                             |    |
| 5901N   | Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack | 3                | 1           | ..         | *405.00                         | 36.10                                      | ImmuCyst                    | SW |
| <b>BACILLUS CALMETTE AND GUERIN-TICE STRAIN</b>   |   |                  |             |            |                                 |  |                             |    |
| <b><u>Restricted benefit</u></b>  |   |                  |             |            |                                 |  |                             |    |
| Primary and relapsing superficial urothelial carcinoma of the bladder   |   |                  |             |            |                                 |  |                             |    |
| 5902P   | Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 x 500 million colony forming units vials                               | 3                | 1           | ..         | 491.83                          | 36.10                                      | OncoTICE                    | MK |

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

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

# VARIOUS

### ALL OTHER THERAPEUTIC PRODUCTS

#### ALL OTHER THERAPEUTIC PRODUCTS

##### *Detoxifying agents for antineoplastic treatment*

#### FOLINIC ACID

##### Note

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

|       |  |    |   |    |         |       |                                   |    |
|-------|--|----|---|----|---------|-------|-----------------------------------|----|
| 1894Q | folinic acid 50 mg/5 mL injection, 5 x 5 mL ampoules | 10 | 2 | .. | *236.10 | 36.10 | <sup>a</sup> Calcium Folate Ebewe | SZ |
|-------|--|----|---|----|---------|-------|-----------------------------------|----|

#### FOLINIC ACID

##### Note

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

|       |   |    |   |    |        |       |  |    |
|-------|---|----|---|----|--------|-------|--|----|
| 1899Y | folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules | 10 | 2 | .. | 236.10 | 36.10 | <sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd) | PF |
|-------|---|----|---|----|--------|-------|--|----|

#### FOLINIC ACID

##### Note

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

|       |  |    |   |    |        |       |  |    |
|-------|--|----|---|----|--------|-------|--|----|
| 1904F | folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules | 10 | 1 | .. | 218.00 | 36.10 | <sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd) | PF |
|-------|--|----|---|----|--------|-------|--|----|

#### FOLINIC ACID

|       |  |   |   |    |        |       |                      |    |
|-------|--|---|---|----|--------|-------|----------------------|----|
| 5863N | folinic acid 1 g/100 mL injection, 1 x 100 mL vial | 1 | 1 | .. | 217.91 | 36.10 | Calcium Folate Ebewe | SZ |
|-------|--|---|---|----|--------|-------|----------------------|----|

|       |   |   |   |    |         |       |   |    |
|-------|---|---|---|----|---------|-------|---|----|
| 5870Y | folinic acid 300 mg/30 mL injection, 1 x 30 mL vial | 4 | 1 | .. | *254.92 | 36.10 | <sup>a</sup> Calcium Folate Ebewe                     | SZ |
|       |   |   |   |    |         |       | <sup>a</sup> Leucovorin Calcium (Hospira Pty Limited) | HH |

#### FOLINIC ACID

##### Note

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

|       |   |    |   |    |         |       |                                   |    |
|-------|---|----|---|----|---------|-------|-----------------------------------|----|
| 5886T | folinic acid 100 mg/10 mL injection, 1 x 10 mL vial | 10 | 1 | .. | *218.00 | 36.10 | <sup>a</sup> Calcium Folate Ebewe | SZ |
|-------|---|----|---|----|---------|-------|-----------------------------------|----|

#### FOLINIC ACID

##### Note

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

|       |  |    |   |    |         |       |   |    |
|-------|--|----|---|----|---------|-------|---|----|
| 5890B | folinic acid 50 mg/5 mL injection, 1 x 5 mL vial | 10 | 2 | .. | *236.10 | 36.10 | <sup>a</sup> Leucovorin Calcium (Hospira Pty Limited) | HH |
|-------|--|----|---|----|---------|-------|---|----|

#### FOLINIC ACID

##### Restricted benefit

Antidote to folic acid antagonists

|       |                               |    |    |    |       |       |                    |    |
|-------|-------------------------------|----|----|----|-------|-------|--------------------|----|
| 5904R | folinic acid 15 mg tablet, 10 | 10 | .. | .. | 76.00 | 36.10 | Leucovorin Calcium | HH |
|-------|-------------------------------|----|----|----|-------|-------|--------------------|----|

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

| Code  | Name, Restriction, Manner of Administration and Form                     | Max. Qty (Packs) | No. of Rpts | Premium \$ | Dispensed Price for Max. Qty \$ | Maximum Recordable Value for Safety Net \$ | Brand Name and Manufacturer |    |
|-------|--|------------------|-------------|------------|---------------------------------|--|-----------------------------|----|
|       |  |                  |             |            |                                 |  | (Hospira Pty Limited)       |    |
|       | <b>MESNA</b>   |                  |             |            |                                 |  |                             |    |
|       | <b><u>Restricted benefit</u></b>   |                  |             |            |                                 |  |                             |    |
|       | Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide |                  |             |            |                                 |  |                             |    |
| 5960Q | mesna 400 mg/4 mL injection, 15 x 4 mL ampoules                          | 15               | 5           | ..         | 81.89                           | 36.10                                      | Uromitexan                  | BX |
| 5961R | mesna 1 g/10 mL injection, 15 x 10 mL ampoules                           | 15               | 5           | ..         | 185.44                          | 36.10                                      | Uromitexan                  | BX |

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*DBL Docetaxel Concentrated Injection (docetaxel 20 mg/2 mL injection, 1 x 2 mL vial) (HH)*

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS..... 16, 17, 18, 19, 50, 51, 52, 53

*DBL Docetaxel Concentrated Injection (docetaxel 80 mg/8 mL injection, 1 x 8 mL vial) (HH)*

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS..... 16, 17, 18, 19, 50, 51, 52, 53

*DBL Epirubicin Hydrochloride Injection (epirubicin hydrochloride 200 mg/100 mL injection, 1 x 100 mL vial) (HH)*

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*DBL Fluorouracil Injection BP (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials) (HH)*

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*DBL Fluorouracil Injection BP (fluorouracil 2.5 g/50 mL injection, 1 x 50 mL vial) (HH)*

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| <i>Gemzar (gemcitabine 200 mg injection, 1 x 200 mg vial) (LY)</i>                 |        |
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| <i>GN-Paclitaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (YA)</i>         |        |
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| <i>GN-Paclitaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (YA)</i>      |        |
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| <i>Hospira Pty Limited (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial) (HH)</i>  |                                |
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| <i>Hospira Pty Limited (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial) (HH)</i>  |                                |
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| <i>Hospira Pty Limited (carboplatin 50 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>   |                                |
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| <i>Hospira Pty Limited (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial) (HH)</i>  |                                |
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| <i>Hospira Pty Limited (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial) (HH)</i>   |                                |

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| <i>Hospira Pty Limited (doxorubicin hydrochloride 10 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>              |                |
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| <i>Hospira Pty Limited (doxorubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>            |                |
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| <i>Hospira Pty Limited (epirubicin hydrochloride 100 mg/50 mL injection, 1 x 50 mL vial) (HH)</i>            |                |
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| <i>Hospira Pty Limited (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (HH)</i>             |                |
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| <i>Hospira Pty Limited (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials) (HH)</i>                       |                |
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| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 40, 74         |
| <i>Hospira Pty Limited (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (HH)</i>    |                |
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| <i>Hospira Pty Limited (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (HH)</i> |                |
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| <i>Hospira Pty Limited (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) (HH)</i>                           |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 11, 45         |
| <i>Hospira Pty Limited (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) (HH)</i>                          |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 11, 45         |
| <i>Hospira Pty Limited (methotrexate 500 mg/20 mL injection, 1 x 20 mL vial) (HH)</i>                        |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 11, 12, 45, 46 |
| <i>Hospira Pty Limited (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (HH)</i>                         |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 22, 56         |
| <i>Hospira Pty Limited (oxaliplatin 100 mg injection, 1 x 100 mg vial) (HH)</i>                              |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 23, 57         |
| <i>Hospira Pty Limited (oxaliplatin 50 mg injection, 1 x 50 mg vial) (HH)</i>                                |                |
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| <i>Hospira Pty Limited (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials) (HH)</i>                 |                |
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| <i>Hospira Pty Limited (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials) (HH)</i>                      |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 14, 48         |
| <i>Hospira Pty Limited (vinorelbine 10 mg/mL injection, 1 x 1 mL vial) (HH)</i>                              |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 15, 49         |
| <i>Hospira Pty Limited (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (HH)</i>                            |                |
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| <i>Hycamtin (topotecan 4 mg injection, 5 x 4 mg vials) (GK)</i>  |                |
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| <i>Idarubicin Ebewe (idarubicin hydrochloride 5 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>       |        |
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| <i>Irinocord (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (WQ)</i>  |        |
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| <i>Irinotecan Actavis (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (TA)</i>        |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 74 |
| <i>Irinotecan Actavis 500 (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (TA)</i> |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 74 |
| <i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (AF)</i>    |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 74 |
| <i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (AF)</i>     |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 74 |
| <i>Irinotecan Alphapharm (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (AF)</i>  |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 74 |
| <i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i>         |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 75 |
| <i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 1 x 15 mL vial) (SZ)</i>       |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 75 |
| <i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (SZ)</i>          |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 75 |
| <i>Irinotecan Ebewe (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (SZ)</i>       |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 75 |
| <i>Irinotecan Kabi (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (PK)</i>          |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 75 |
| <i>Irinotecan Kabi (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (PK)</i>           |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....   | 40, 75 |

## J

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| <i>Jevtana (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1) (SW)</i> |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....  | 15, 49 |

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| <i>Leucovorin Calcium (Pfizer Australia Pty Ltd) (PF)</i>  |        |
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| <i>Leustatin (cladribine 10 mg/10 mL injection, 1 x 10 mL vial) (JC)</i>                                     |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....  | 12, 46 |
| <i>Lipodox (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial) (ZF)</i>    |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....  | 21, 55 |
| <i>Lipodox 50 (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial) (ZF)</i> |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....  | 21, 55 |
| <i>Litak (cladribine 10 mg/5 mL injection, 1 x 5 mL vial) (OA)</i>   |        |
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## M

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| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....                                 | 25, 59, 60     |
| <i>Mabthera (rituximab 500 mg/50 mL injection, 1 x 50 mL vial) (RO)</i>           |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....                                 | 25, 26, 59, 60 |
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| <i>Methaccord (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (WQ)</i>         |                |
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| <i>Methaccord (METHOTREXATE Injection 50 mg in 2 mL, 1) (WQ)</i>                  |                |
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| <i>Methotrexate Ebewe (methotrexate 1 g/10 mL injection, 1 x 10 mL vial) (SZ)</i> |                |

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| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 11, 12, 45, 46 |
| <i>Methotrexate Ebewe (methotrexate 5 g/50 mL injection, 1 x 50 mL vial) (SZ)</i>  |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 11, 12, 45, 46 |
| <b>MITOZANTRONE</b>  |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 22, 56         |
| <i>Mitozantrone Ebewe (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (SZ)</i>  |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 22, 56         |
| <i>Muphoran (fotemustine 208 mg injection [1 x 208 mg vial] (&amp;) inert substance diluent [1 x 4 mL ampoule], 1 pack) (SE)</i> |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 11, 45         |

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| <i>Navelbine (vinorelbine 10 mg/mL injection, 1 x 1 mL vial) (FB)</i>   |        |
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| <i>Navelbine (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (FB)</i> |        |
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| <i>Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 1 x 5 mL vial) (OE)</i> |                                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 41, 75                         |
| <i>Omegapharm Irinotecan (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 1 x 2 mL vial) (OE)</i>  |                                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 41, 75                         |
| <i>Oncotaxel 140 (docetaxel 140 mg/7 mL injection, 1 x 7 mL vial) (TA)</i>                                   |                                |
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| <i>Oncotaxel 80 (docetaxel 80 mg/4 mL injection, 1 x 4 mL vial) (TA)</i>                                     |                                |
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| <i>Onkotrone (mitozantrone 25 mg/12.5 mL injection, 1 x 12.5 mL vial) (BX)</i>                               |                                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 22, 56                         |
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| .ALIMENTARY TRACT AND METABOLISM .....   | 79                             |
| <i>Oxallicord (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (WQ)</i>                                  |                                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 23, 57                         |
| <i>Oxallicord (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (WQ)</i>                                   |                                |
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## OXALIPLATIN

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| <i>Oxaliplatin Ebewe (oxaliplatin 100 mg injection, 1 x 100 mg vial) (SZ)</i>      |        |
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| <i>Oxaliplatin Kabi (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (PK)</i>  |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....                                  | 24, 58 |
| <i>Oxaliplatin Kabi (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (PK)</i>   |        |
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| <i>Oxaliplatin SUN (oxaliplatin 100 mg/20 mL injection, 1 x 20 mL vial) (ZF)</i>   |        |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....                                  | 24, 58 |
| <i>Oxaliplatin SUN (oxaliplatin 200 mg/40 mL injection, 1 x 40 mL vial) (ZF)</i>   |        |
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| <i>Oxaliplatin SUN (oxaliplatin 50 mg/10 mL injection, 1 x 10 mL vial) (ZF)</i>    |        |
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| <i>Paclitaxel Actavis (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (TA)</i>           |        |
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| <i>Paclitaxel Actavis (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (TA)</i>        |        |
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| <i>Paclitaxel Ebewe (paclitaxel 100 mg/16.7 mL injection, 1 x 16.7 mL vial) (SZ)</i>      |        |
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| <i>Paclitaxel Ebewe (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials) (SZ)</i>            |        |
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| <i>Paclitaxel Pfizer (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (PF)</i>            |        |
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| <i>Paclitaxel Pfizer (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (PF)</i>         |        |
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| <i>Pfizer Australia Pty Ltd (carboplatin 150 mg/15 mL injection, 1 x 15 mL vial) (PF)</i> |        |
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| <i>Pfizer Australia Pty Ltd (carboplatin 450 mg/45 mL injection, 1 x 45 mL vial) (PF)</i> |        |

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| <i>Pfizer Australia Pty Ltd (cisplatin 100 mg/100 mL injection, 1 x 100 mL vial) (PF)</i>           |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....  | 23, 57         |
| <i>Pfizer Australia Pty Ltd (cisplatin 50 mg/50 mL injection, 1 x 50 mL vial) (PF)</i>              |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....  | 23, 57         |
| <i>Pfizer Australia Pty Ltd (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials) (PF)</i>             |                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....  | 13, 47         |
| <i>Pfizer Australia Pty Ltd (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) (PF)</i>            |                |
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| <i>Pfizer Australia Pty Ltd (mitozantrone 20 mg/10 mL injection, 1 x 10 mL vial) (PF)</i>           |                |
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| <i>Pharmorubicin Solution (epirubicin hydrochloride 50 mg/25 mL injection, 1 x 25 mL vial) (PF)</i> |                |
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| <i>Phenasen (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) (PL)</i>                     |                |
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| <i>Plaxel (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (WQ)</i>                                 |                |
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| <i>Plaxel (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (WQ)</i>                              |                |
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| <i>Taxol (paclitaxel 30 mg/5 mL injection, 1 x 5 mL vial) (BQ)</i>   |                                |
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| <i>Taxol (paclitaxel 300 mg/50 mL injection, 1 x 50 mL vial) (BQ)</i>  |                                |
| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....   | 20, 54                         |
| <i>Taxotere (docetaxel 20 mg/mL injection, 1 x 1 mL vial) (SW)</i>   |                                |
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| <i>Taxotere (docetaxel 80 mg/2 mL injection [1 x 2 mL vial] (&amp; inert substance diluent [1 x 6 mL vial], 1 pack) (SW)</i> |                                |
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| <i>Tecan (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 1 x 25 mL vial) (WQ)</i>                               |                                |
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| .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS .....                               | 31, 39, 40, 65, 67, 74         |
| <i>Velcade (bortezomib 3.5 mg injection, 1 x 3.5 mg vial) (JC)</i>              |                                |
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| <i>Vinorelbine Ebewe (vinorelbine 50 mg/5 mL injection, 1 x 5 mL vial) (SZ)</i> |                                |
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| <i>Xalox (oxaliplatin 100 mg injection, 1 x 100 mg vial) (WQ)</i> |        |
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| <i>Xalox (oxaliplatin 50 mg injection, 1 x 50 mg vial) (WQ)</i>   |        |
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## Z

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