Schedule of Pharmaceutical Benefits

Efficient Funding of Chemotherapy

Effective 1 December 2020
## Contents

Summary of Changes .............................................................................................................................................. 3

About the Supplement .............................................................................................................................................. 6

Symbols used in the Efficient Funding of Chemotherapy supplement .............................................................. 6

Remuneration arrangements .................................................................................................................................. 6

**Pharmaceutical Benefits Schedules** ...................................................................................................................... 7

Chemotherapy items for Private Hospital use ........................................................................................................ 9

Chemotherapy items for Public Hospital use .......................................................................................................... 75

Related Pharmaceutical Benefits for Public Hospital use ..................................................................................... 143

**Index of Manufacturers’ Code** ........................................................................................................................ 153

**Generic/Proprietary Index** .............................................................................................................................. 155
Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2020. The Schedule is updated on the first day of each month and is available on the internet at [www.pbs.gov.au](http://www.pbs.gov.au).

**Efficient Funding of Chemotherapy (Private Hospital)**

**Additions**

<table>
<thead>
<tr>
<th>Addition – Item</th>
<th>OBINUTUZUMAB, obinutuzumab 1 g/40 mL injection, 40 mL vial (Gazyva)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12193R</td>
<td>-</td>
</tr>
</tbody>
</table>

**Addition – Brand**

<table>
<thead>
<tr>
<th>Addition – Brand</th>
<th>Arsenic Trioxide Juno, JU – ARSENIC, arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>10699D</td>
<td>-</td>
</tr>
<tr>
<td>7241D</td>
<td>-</td>
</tr>
</tbody>
</table>

**Deletions**

<table>
<thead>
<tr>
<th>Deletion – Brand</th>
<th>Oxaliplatin SUN, RA – OXALIPLATIN, oxaliplatin 50 mg/10 mL injection, 10 mL vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>7253R</td>
<td>-</td>
</tr>
</tbody>
</table>

**Alterations**

**Alteration – Note**

<table>
<thead>
<tr>
<th>Alteration – Note</th>
<th>OBINUTUZUMAB, obinutuzumab 1 g/40 mL injection, 40 mL vial (Gazyva)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10418H</td>
<td>-</td>
</tr>
</tbody>
</table>

**Alteration – Restriction**

<table>
<thead>
<tr>
<th>Alteration – Restriction</th>
<th>OBINUTUZUMAB, obinutuzumab 1 g/40 mL injection, 40 mL vial (Gazyva)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10418H</td>
<td>-</td>
</tr>
</tbody>
</table>

**Alteration – Manufacturer Code**

<table>
<thead>
<tr>
<th>Alteration – Manufacturer Code</th>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>10383L Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>10402L Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>10589H Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>10597R Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>7264H Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>7265J Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>7266K Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
<tr>
<td>7267L Ontruzant – TRASTUZUMAB</td>
<td>MK</td>
<td>OQ</td>
</tr>
</tbody>
</table>

**Supply only**

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules.

Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it was deleted.

Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at [www.pbs.gov.au](http://www.pbs.gov.au).

**Supply Only commencing 1 December 2020**

<table>
<thead>
<tr>
<th>Supply Only</th>
<th>Bleomycin for Injection, USP – BLEOMYCIN, bleomycin sulfate 15 000 international units injection, 1 vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>11701W</td>
<td>-</td>
</tr>
</tbody>
</table>
Advance Notices
1 January 2021

Deletion – Brand

7234R  DBL Fluorouracil Injection BP, PF – FLUOROURACIL, fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials
7239B  DBL Fluorouracil Injection BP, PF – FLUOROURACIL, fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials
7254T  Anzatax, PF – PACLITAXEL, paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial
7254T  Anzatax, PF – PACLITAXEL, paclitaxel 150 mg/25 mL injection, 25 mL vial
7254T  Anzatax, PF – PACLITAXEL, paclitaxel 300 mg/50 mL injection, 50 mL vial
7255W  Alimta, LY – PEMETREXED, pemetrexed 500 mg injection, 1 vial
7275W  Alimta, LY – PEMETREXED, pemetrexed 100 mg injection, 1 vial

Efficient Funding of Chemotherapy (Public Hospital)

Additions

Addition – Item
12204H  OVINUTUZUMAB, obinutuzumab 1 g/40 mL injection, 40 mL vial (Gazyva)

Addition – Brand
10691Q  Arsenic Trioxide Juno, JU – ARSENIC, arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials
4371C  Arsenic Trioxide Juno, JU – ARSENIC, arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials

Deletions

Deletion – Brand
4542C  Oxaliplatin SUN, RA – OXALIPLATIN, oxaliplatin 50 mg/10 mL injection, 10 mL vial

Alterations

Alteration – Note
10407R  OVINUTUZUMAB, obinutuzumab 1 g/40 mL injection, 40 mL vial (Gazyva)

Alteration – Restriction
10407R  OVINUTUZUMAB, obinutuzumab 1 g/40 mL injection, 40 mL vial (Gazyva)

Alteration – Manufacturer Code

10391X  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
10401K  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
10581X  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
10588G  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
4632T  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
4639E  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
4650R  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial
4703M  Ontruzant – TRASTUZUMAB, trastuzumab 150 mg injection, 1 vial

Supply Only

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it was deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only commencing 1 December 2020
11704B  Bleomycin for Injection, USP – BLEOMYCIN, bleomycin sulfate 15 000 international units injection, 1 vial
### Advance Notices

1 January 2021

**Deletion – Brand**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4394G</td>
<td>DBL Fluorouracil Injection BP, PF – FLUOROURACIL, fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials</td>
</tr>
<tr>
<td>4431F</td>
<td>DBL Fluorouracil Injection BP, PF – FLUOROURACIL, fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials</td>
</tr>
<tr>
<td>4567J</td>
<td>Anzatax, PF – PACLITAXEL, paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial</td>
</tr>
<tr>
<td>4567J</td>
<td>Anzatax, PF – PACLITAXEL, paclitaxel 150 mg/25 mL injection, 25 mL vial</td>
</tr>
<tr>
<td>4567J</td>
<td>Anzatax, PF – PACLITAXEL, paclitaxel 300 mg/50 mL injection, 50 mL vial</td>
</tr>
<tr>
<td>4600D</td>
<td>Alimta, LY – PEMETREXED, pemetrexed 500 mg injection, 1 vial</td>
</tr>
<tr>
<td>4600D</td>
<td>Alimta, LY – PEMETREXED, pemetrexed 100 mg injection, 1 vial</td>
</tr>
</tbody>
</table>
About the Supplement

The Schedule of Pharmaceutical Benefits – Efficient Funding of Chemotherapy supplement lists items distributed under section 100 of the National Health Act 1953.

The Supplement is published and is effective on the first day of each month. For detailed information about the prescribing and supply of chemotherapy benefits go to www.pbs.gov.au.

For information about the operational aspects of the Efficient Funding of Chemotherapy, such as, claiming, authority applications and stationery supplies contact the Department of Human Services at www.humanservices.gov.au.

This supplement is split into three parts:

Chemotherapy items for private hospital use. This includes items subject to the revised arrangements, ie. chemotherapy drugs administered through infusion or injection

Chemotherapy items for public hospital use. This includes items subject to the revised arrangements, ie. chemotherapy drugs administered through infusion or injection

PBS products available for private and public hospital use may be dispensed in accordance with the relevant section 100 special arrangements through community pharmacy.

Related pharmaceutical benefits for public hospital use. This includes items such as antiemetics, antinauseants, immunostimulants and detoxifying agents for antineoplastic treatment

Symbols used in the Efficient Funding of Chemotherapy supplement

* An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity

‡ A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed

a or b Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect

Remuneration arrangements

Fees payable per item claimed:

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

- Ready Prepared Dispensing Fee ($7.74)
- Preparation fee ($85.78)
- Distribution fee ($27.45)
- Diluent fee ($5.44)

Section 94 Approved Public Hospital Authority

- Preparation fee ($85.78)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee ($7.74)
- Preparation fee ($85.78)
- Distribution fee ($27.45) (not payable where the drug is trastuzumab)
- Diluent fee ($5.44)
Pharmaceutical Benefits Schedules
### Chemotherapy items for Private Hospital use

**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS** .......................................................... 10

**ANTINEOPLASTIC AGENTS** ........................................................................................................ 10
**ALKYLATING AGENTS** ............................................................................................................. 10
**ANTIMETABOLITES** .................................................................................................................. 11
**PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS** ..................................................... 13
**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES** ................................................... 15
**OTHER ANTINEOPLASTIC AGENTS** ........................................................................................ 17
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

BENDAMUSTINE

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

Authority required (STREAMLINED)

7972
Previously untreated stage III or IV mantle cell lymphoma
Treatment Phase: Induction treatment
Clinical criteria:
- The condition must be CD20 positive, AND
- The treatment must be in combination with rituximab, AND
- The condition must be previously untreated, AND
- The condition must be symptomatic, AND
- The treatment must be for induction treatment purposes only, AND
- Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction, AND
- Patient must not be eligible for stem cell transplantation.

Authority required (STREAMLINED)

7943
Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma
Treatment Phase: Induction treatment
Clinical criteria:
- The condition must be CD20 positive, AND
- The condition must be previously untreated, AND
- The condition must be symptomatic, AND
- The treatment must be for induction treatment purposes only, AND
- The treatment must be in combination with rituximab or obinutuzumab, AND
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

Authority required (STREAMLINED)

7944
Follicular lymphoma
Treatment Phase: Re-induction treatment
Clinical criteria:
- The condition must be CD20 positive, AND
- The condition must be refractory to treatment with rituximab for this condition, AND
- The condition must be symptomatic, AND
- The treatment must be for re-induction treatment purposes only, AND
- The treatment must be in combination with obinutuzumab, AND
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.
The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.

Injection
10763L

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>*1763.65</td>
<td>41.00</td>
<td>Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

CYCLOPHOSPHAMIDE

Injection
7226H

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2800 mg</td>
<td>17</td>
<td>..</td>
<td>*199.10</td>
<td>41.00</td>
<td>Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Endoxan [BX] (cyclophosphamide 500 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

IFOSFAMIDE

Injection
7248L

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4000 mg</td>
<td>19</td>
<td>..</td>
<td>*325.81</td>
<td>41.00</td>
<td>Holoxan [BX] (ifosfamide 1 g injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Holoxan [BX] (ifosfamide 2 g injection, 1 vial)</td>
</tr>
</tbody>
</table>

Nitrosoureas
### FOTEMUSTINE

**Authority required (STREAMLINED)**

6288

Metastatic malignant melanoma

<table>
<thead>
<tr>
<th>Injection 7245H</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>220 mg</td>
<td>8</td>
<td>..</td>
<td>*1912.57</td>
<td>41.00</td>
<td>Muphoran [SE] (fotemustine 208 mg injection [1 vial] &amp; inert substance diluent [4 mL ampoule], 1 pack)</td>
<td></td>
</tr>
</tbody>
</table>

### ANTIMETABOLITES

**Folic acid analogues**

### METHOTREXATE

#### Injection 7250N

**Max. Amount | No. of Rpts | Premium $ | DPMA $ | MRVSN $ | Brand Name and Manufacturer**

| 250 mg | 5 | .. | *152.28 | 41.00 | DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) |
| 500 mg | 5 | .. | .. | .. | DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) |
| 50 mg  | 5 | .. | .. | .. | DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) |
| 1000 mg| 5 | .. | .. | .. | Methotrexate Accord [OD] (methotrexate 1000 mg/10 mL injection, 10 mL vial) |

#### Injection 7251P

**Max. Amount | No. of Rpts | Premium $ | DPMA $ | MRVSN $ | Brand Name and Manufacturer**

| 20000 mg | .. | .. | *890.37 | 41.00 | DBL Methotrexate [PF] (methotrexate 20000 mg/10 mL injection, 10 mL vial) |
| 1000 mg  | .. | .. | .. | .. | DBL Methotrexate [PF] (methotrexate 1000 mg/2 mL injection, 5 x 2 mL vials) |
| 500 mg   | .. | .. | .. | .. | DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) |
| 50 mg    | .. | .. | .. | .. | Methotrexate Accord [OD] (methotrexate 500 mg/10 mL injection, 10 mL vial) |

#### Injection 7255W

**Max. Amount | No. of Rpts | Premium $ | DPMA $ | MRVSN $ | Brand Name and Manufacturer**

| 1100 mg  | 5 | .. | *228.98 | 41.00 | Alimta [LY] (pemetrexed 1100 mg injection, 1 vial) |
| 500 mg   | .. | .. | .. | .. | Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial) |
| 100 mg   | .. | .. | .. | .. | Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial) |
| 50 mg    | .. | .. | .. | .. | Pemetrexed APOTEX [TX] (pemetrexed 500 mg injection, 1 vial) |
### PRALATREXATE

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

**Authority required**
Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma
Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be relapsed or chemotherapy refractory, **AND**
- Patient must have undergone appropriate prior front-line curative intent chemotherapy.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 mg</td>
<td>5</td>
<td>..</td>
<td>4547.45</td>
<td>41.00</td>
<td>Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)</td>
</tr>
</tbody>
</table>

### PRALATREXATE

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

**Authority required**
Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma
Treatment Phase: Continuing treatment

**Clinical criteria:**
- The condition must be relapsed or chemotherapy refractory, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 mg</td>
<td>11</td>
<td>..</td>
<td>4547.45</td>
<td>41.00</td>
<td>Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)</td>
</tr>
</tbody>
</table>

### RALTITREXED

**Authority required (STREAMLINED)**
6228
Advanced colorectal cancer

**Clinical criteria:**
- The treatment must only be used as a single agent in the treatment of this condition.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 mg</td>
<td>8</td>
<td>..</td>
<td>1183.85</td>
<td>41.00</td>
<td>Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### Purine analogues

### CLADRIBINE

**Authority required (STREAMLINED)**
6265
Hairy cell leukaemia

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 mg</td>
<td>6</td>
<td>..</td>
<td>1181.41</td>
<td>41.00</td>
<td>Leustatin [JC] (cladribine 10 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Litak [AF] (cladribine 10 mg/5 mL injection, 5 mL vial)</td>
</tr>
</tbody>
</table>

### FLUDARABINE

**Note** Pharmaceutical benefits that have the form fludarabine phosphate 50 mg injection and pharmaceutical benefits that have the form fludarabine phosphate 50 mg/2 mL injection are equivalent for the purposes of substitution.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 mg</td>
<td>29</td>
<td>..</td>
<td>190.99</td>
<td>41.00</td>
<td>Fludarabine AMNEAL [JU] (fludarabine phosphate 50 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)</td>
</tr>
</tbody>
</table>
## Pyrimidine analogues

### CYTARABINE

**Injection 7227J**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>7000 mg</td>
<td>15</td>
<td>..</td>
<td>*935.61</td>
<td>41.00</td>
<td>Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)</td>
</tr>
</tbody>
</table>

### FLUOROURACIL

**Restricted benefit**

Patients requiring administration of fluorouracil by intravenous infusion

**Injection 7234R**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5500 mg</td>
<td>11</td>
<td>..</td>
<td>*165.96</td>
<td>41.00</td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

### FLUOROURACIL

**Restricted benefit**

Patients requiring administration of fluorouracil by intravenous injection

**Injection 7239B**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>23</td>
<td>..</td>
<td>*133.60</td>
<td>41.00</td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

### GEMCITABINE

**Caution** Pharmaceutical benefits containing gemcitabine may have different concentrations.

**Injection 7246J**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mg</td>
<td>17</td>
<td>..</td>
<td>*190.34</td>
<td>41.00</td>
<td>DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)</td>
</tr>
</tbody>
</table>

## PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

*Vinca alkaloids and analogues*
### VINBLASTINE

**Injection 7261E**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mg</td>
<td>17</td>
<td>..</td>
<td>*200.77</td>
<td>41.00</td>
<td>DBL Vinblastine [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)</td>
</tr>
</tbody>
</table>

### VINCRISTINE

**Injection 7262F**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mg</td>
<td>7</td>
<td>..</td>
<td>*144.49</td>
<td>41.00</td>
<td>DBL Vincristine Sulfate [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)</td>
</tr>
</tbody>
</table>

### VINORELBINE

**Injection 7263G**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| 70 mg       | 7           | ..        | *198.30| 41.00   | Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial)  
Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial)  
Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial)  
Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial) |

**Podophyllotoxin derivatives**

### ETOPOSIDE

**Injection 7237X**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| 440 mg      | 14          | ..        | *322.61| 41.00   | Etopophos [LM] (etoposide phosphate 1.136 g (etoposide 1 g injection, 1 vial)  
Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)  
Pfizer Australia Pty Ltd [PF] (etoposide 100 mg/5 mL injection, 5 mL vial) |

### Taxanes

#### CABAZITAXEL

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED) 4662**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with prednisone or prednisolone, **AND**
- The treatment must not be used in combination with abiraterone, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.

**Injection 7236W**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 mg</td>
<td>5</td>
<td>..</td>
<td>*3016.31</td>
<td>41.00</td>
<td>Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&amp;) inert substance diluent [4.5 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

#### DOCETAXEL

**Note** Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 160 mg in 8 mL and docetaxel solution concentrate for I.V. infusion 160 mg in 16 mL are equivalent for the purposes of substitution.

**Injection 10158P**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| 250 mg      | 5           | ..        | *224.25| 41.00   | DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial)  
DBL Docetaxel Concentrated Injection [PF] (docetaxel 80 mg/8 mL injection, 8 mL vial)  
Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial)  
Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial) |
### NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

**Authority required (STREAMLINED)**

- **6106**
  - Metastatic breast cancer
- **6119**
  - HER2 positive breast cancer

#### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>580 mg</td>
<td>5</td>
<td>..</td>
<td>*2214.89</td>
<td>41.00</td>
<td>Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**Note** Special Pricing Arrangements apply.

**Note** Not for use as neoadjuvant or adjuvant therapy.

**Authority required (STREAMLINED)**

- **4657**
  - Stage IV (metastatic) adenocarcinoma of the pancreas

#### Clinical criteria:

- The treatment must be in combination with gemcitabine, **AND**
- The condition must not have been treated previously with PBS-subsidised therapy, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less.

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

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>275 mg</td>
<td>11</td>
<td>..</td>
<td>*1170.65</td>
<td>41.00</td>
<td>Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### PACLITAXEL

#### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>450 mg</td>
<td>3</td>
<td>..</td>
<td>*201.93</td>
<td>41.00</td>
<td>Anzatax [PF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Anzatax [PF] (paclitaxel 150 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Anzatax [PF] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Ebeve [SZ] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Kabi [PK] (paclitaxel 30 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Kabi [PK] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 150 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 30 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

#### Anthracyclines and related substances

### DOXORUBICIN

#### Injection/intravesical

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>135 mg</td>
<td>11</td>
<td>..</td>
<td>*178.28</td>
<td>41.00</td>
<td>Adriamycin [PF] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

### DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

**Authority required (STREAMLINED)**

- **4786**
  - Advanced epithelial ovarian cancer

#### Clinical criteria:
- Patient must have failed a first-line platinum-based chemotherapy regimen.

**Authority required (STREAMLINED)**

4791
Metastatic breast cancer

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have failed prior therapy which included capecitabine and a taxane.

**Authority required (STREAMLINED)**

4787
Metastatic breast cancer

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have a contraindication to therapy with capecitabine and/or a taxane.

### Injection

**7230M**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg</td>
<td>5</td>
<td>..</td>
<td>*1205.29</td>
<td>41.00</td>
<td>Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
</tbody>
</table>

### EPIRUBICIN

**Injection/intravesical**

**7231N**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>220 mg</td>
<td>5</td>
<td>..</td>
<td>*207.76</td>
<td>41.00</td>
<td>Epirube [TB] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirube [TB] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin ACT [JU] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin ACT [JU] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin ACT [JU] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
</tbody>
</table>

### IDARUBICIN

**Restricted benefit**

**Acute myelogenous leukaemia (AML)**

**Injection**

**7247K**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>5</td>
<td>..</td>
<td>*260.39</td>
<td>41.00</td>
<td>Zavedos Solution [PF] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)</td>
</tr>
</tbody>
</table>

### MITOZANTRONE

**Injection**

**7252Q**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>5</td>
<td>..</td>
<td>*220.31</td>
<td>41.00</td>
<td>Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Onkotrone [BX] (mitozantrone 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Onkotrone [BX] (mitozantrone 25 mg/12.5 mL injection, 12.5 mL vial)</td>
</tr>
</tbody>
</table>

### Other cytotoxic antibiotics

### BLEOMYCIN

**Restricted benefit**

**Germ cell neoplasms**

**Restricted benefit**

**Lymphoma**
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

#### CHEMOTHERAPY ITEMS FOR PRIVATE HOSPITAL USE

<table>
<thead>
<tr>
<th>Injection</th>
<th>7244G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>30000 IU</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>11</td>
</tr>
<tr>
<td>Premium $</td>
<td>*207.53</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial)</td>
<td></td>
</tr>
<tr>
<td>DBL Bleomycin Sulfate [PF] (bleomycin sulfate 15 000 international units injection, 1 vial)</td>
<td></td>
</tr>
</tbody>
</table>

### OTHER ANTINEOPLASTIC AGENTS

#### platinum compounds

### CARBOPLATIN

<table>
<thead>
<tr>
<th>Injection</th>
<th>7222D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>900 mg</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>5</td>
</tr>
<tr>
<td>Premium $</td>
<td>*198.39</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial)</td>
<td></td>
</tr>
<tr>
<td>DBL Carboplatin [PF] (carboplatin 150 mg/15 mL injection, 15 mL vial)</td>
<td></td>
</tr>
<tr>
<td>DBL Carboplatin [PF] (carboplatin 450 mg/45 mL injection, 45 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

### CISPLATIN

<table>
<thead>
<tr>
<th>Injection</th>
<th>7224F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>220 mg</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>14</td>
</tr>
<tr>
<td>Premium $</td>
<td>*176.07</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial)</td>
<td></td>
</tr>
<tr>
<td>Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

### OXALIPLATIN

<table>
<thead>
<tr>
<th>Injection</th>
<th>7253R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>300 mg</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>11</td>
</tr>
<tr>
<td>Premium $</td>
<td>*186.46</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>DBL Oxaliplatin Concentrate [PF] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)</td>
<td></td>
</tr>
<tr>
<td>Oxaliplatin Accord [OC] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)</td>
<td></td>
</tr>
<tr>
<td>Oxaliplatin SUN [RA] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)</td>
<td></td>
</tr>
<tr>
<td>Oxaliplatin SUN [RA] (oxaliplatin 200 mg/40 mL injection, 40 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

### monoclonal antibodies

### ATEZOLIZUMAB

- **Note**: No increase in the maximum number of repeats may be authorised.
- **Note**: Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

<table>
<thead>
<tr>
<th>Injection</th>
<th>10297</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally advanced or metastatic non-small cell lung cancer</td>
<td></td>
</tr>
<tr>
<td>Treatment Phase: Continuing treatment - 3 weekly treatment regimen</td>
<td></td>
</tr>
<tr>
<td>Clinical criteria:</td>
<td></td>
</tr>
<tr>
<td>- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND</td>
<td></td>
</tr>
<tr>
<td>- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, AND</td>
<td></td>
</tr>
<tr>
<td>- Patient must have stable or responding disease.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injection</th>
<th>11297N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>1200 mg</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>7</td>
</tr>
<tr>
<td>Premium $</td>
<td>*7328.33</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

- **Note**: No increase in the maximum number of repeats may be authorised.
- **Note**: Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

<table>
<thead>
<tr>
<th>Injection</th>
<th>10215</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally advanced or metastatic non-small cell lung cancer</td>
<td></td>
</tr>
<tr>
<td>Treatment Phase: Continuing treatment - 4 weekly treatment regimen</td>
<td></td>
</tr>
<tr>
<td>Clinical criteria:</td>
<td></td>
</tr>
<tr>
<td>- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND</td>
<td></td>
</tr>
<tr>
<td>- The treatment must be the sole PBS-subsidised therapy for this condition, AND</td>
<td></td>
</tr>
</tbody>
</table>
- Patient must have stable or responding disease.

### ATEZOLIZUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10257**

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing first-line treatment of metastatic disease, as monotherapy, where concomitant bevacizumab has ceased due to intolerance - 4 weekly treatment regimen

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>5</td>
<td>..</td>
<td>*10209.09 41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10276**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 3 weekly treatment regimen

**Clinical criteria:**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>5</td>
<td>..</td>
<td>*7328.33 41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10206**

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be previously untreated, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>3</td>
<td>..</td>
<td>*7328.33 41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
<td></td>
</tr>
</tbody>
</table>

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)
10312**
Locally advanced or metastatic non-small cell lung cancer
Treatment Phase: Initial treatment - 4 weekly treatment regimen

**Clinical criteria:**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy.

**Injection 11940K**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>3</td>
<td>..</td>
<td>*10209.09</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**ATEZOLIZUMAB**

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)
10509**
Extensive-stage small cell lung cancer
Treatment Phase: Continuing treatment - 4 weekly treatment regimen

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Injection 12076N**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>3</td>
<td>..</td>
<td>*10209.09</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**ATEZOLIZUMAB**

Note No increase in the maximum amount or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)
10917**
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.
- PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

**Injection 12155R**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>8</td>
<td>..</td>
<td>*7328.33</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**ATEZOLIZUMAB**

Note No increase in the maximum amount or number of units may be authorised.
Note Increased repeats of up to 11 may be requested for doses of 840 mg administered every 2 weeks
Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)
10972**
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.
- PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time
### ATEZOLIZUMAB

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

#### 10182
Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Initial treatment 1

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

**Clinical criteria:**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
- Patient must have not previously been treated for this condition in the metastatic setting, AND
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

**Authority required (STREAMLINED)**

#### 10125
Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Initial treatment 2

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

**Clinical criteria:**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
- Patient must have a WHO performance status of 0 or 1, AND
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, AND
- Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI), AND
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer.

**Authority required (STREAMLINED)**

#### 9345
Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Grandfathering treatment

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.

**Clinical criteria:**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND

---

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
<th><strong>Max. Amount</strong></th>
<th><strong>No. of Rpts</strong></th>
<th><strong>Premium $</strong></th>
<th><strong>DPMA $</strong></th>
<th><strong>MRVSN $</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>12159Y</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
<td>1680 mg</td>
<td>5</td>
<td>..</td>
<td>*10209.09</td>
<td>41.00</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
<th><strong>Max. Amount</strong></th>
<th><strong>No. of Rpts</strong></th>
<th><strong>Premium $</strong></th>
<th><strong>DPMA $</strong></th>
<th><strong>MRVSN $</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>11792P</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
<td>1200 mg</td>
<td>5</td>
<td>..</td>
<td>*7328.33</td>
<td>41.00</td>
</tr>
</tbody>
</table>
Chemotherapy items for Private Hospital use

- Patient must have previously received treatment with these drugs for this condition prior to 1 October 2019, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have a WHO performance status of 0 or 1.

**Note:** Patients may qualify for PBS-subsidised treatment under this restriction only. For continuing PBS-subsidised treatment, a ‘Grandfathered’ patient must qualify under the ‘Continuing treatment’ criteria.

### Injection 11801D

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>7</td>
<td>..</td>
<td>*7328.33</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

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

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

**Note:** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 10521

Extensive-stage small cell lung cancer

**Treatment Phase:** Continuing treatment - 3 weekly treatment regimen

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Authority required (STREAMLINED)**

#### 10204

Extensive-stage small cell lung cancer

**Treatment Phase:** Grandfather treatment

**Clinical criteria:**
- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2020, **AND**
- The condition must have been untreated prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must have had a WHO performance status of 0 or 1 at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
- The treatment must be in combination with etoposide and a platinum-based antineoplastic if the patient is yet to complete their first 4 cycles of treatment; OR
- The treatment must be as monotherapy if being administered as maintenance therapy.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

### Injection 11928T

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>4</td>
<td>..</td>
<td>*7328.33</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

**Note:** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note:** No increase in the maximum amount or number of units may be authorised.

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

**Note:** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 10915

Advanced ( unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

**Treatment Phase:** Transitioning from non-PBS-subsidised to PBS-subsidised supply - Grandfather treatment - 3 weekly treatment regimen (1,200 mg) or 4 weekly treatment regimen (1,680 mg where bevacizumab is discontinued)

**Clinical criteria:**
- Patient must have commenced non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 November 2020, **AND**
- Patient must have met all the PBS eligibility criteria applying to a non-grandfather patient under the Initial treatment restriction for this PBS indication prior to having commenced non-PBS-subsidised treatment with this drug, which are: (i) WHO status score no greater than 1, (ii) Child Pugh class A chronic liver disease, (iii) the patient was unsuitable for transarterial chemoembolization, (iv) the condition was untreated with systemic therapy, unless an intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal had occurred, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.
A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

### Injection 12163E

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>5</td>
<td>...</td>
<td>*10209.09</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

**Caution** The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum amount or number of units may be authorised.

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED) 10939

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.

**Clinical criteria:**
- Patient must have a WHO performance status of 0 or 1, AND
- Patient must not be suitable for transarterial chemoembolisation, AND
- Patient must have Child Pugh class A, AND
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

### Injection 12167J

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>3</td>
<td>...</td>
<td>*7328.33</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

### AVELUMAB

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED) 8947

Stage IV (metastatic) Merkel Cell Carcinoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.

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

### Injection 11679Q

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>8</td>
<td>...</td>
<td>*8384.57</td>
<td>41.00</td>
<td>Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)</td>
</tr>
</tbody>
</table>

### AVELUMAB

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED) 10023

Stage IV (metastatic) Merkel Cell Carcinoma

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while being treated with this drug for this condition, AND
- The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction.
### BEVACIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 4584

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer  
Treatment Phase: Continuing treatment  
Clinical criteria:  
- Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition, **AND**  
- Patient must not have progressive disease, **AND**  
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks, **AND**  
- The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11685B</td>
<td>1200 mg</td>
<td>11</td>
<td>..</td>
<td>*8384.57</td>
<td>41.00</td>
<td>Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)</td>
</tr>
</tbody>
</table>

### BEVACIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 4814

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer  
Treatment Phase: Initial treatment  
Clinical criteria:  
- The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm) only if the patient presents with Stage IIIB or Stage IIIC disease, **AND**  
- Patient must have a WHO performance status of 2 or less, **AND**  
- The condition must be previously untreated, **AND**  
- The treatment must be commenced in combination with platinum-based chemotherapy, **AND**  
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks, **AND**  
- The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.  
The patient’s WHO performance status and body weight must be documented in the patient’s medical records at the time the treatment cycle is initiated.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10114H</td>
<td>900 mg</td>
<td>11</td>
<td>..</td>
<td>*2900.15</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

### BEVACIZUMAB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

#### 6337

Advanced carcinoma of cervix  
Treatment Phase: Initial treatment  
Clinical criteria:  
- Patient must have a Gynaecologic Oncology Group (GOG) performance status of 0 or 1, **AND**  
- The condition must not be amenable to curative treatment with surgery; **OR**  
- The condition must not be amenable to curative radiation therapy, **AND**  
- The condition must be previously untreated with this drug, **AND**  
- Patient must not have received prior chemotherapy; **OR**  
- Patient must have received prior chemotherapy with radiation therapy, **AND**  
- The treatment must be in combination with platinum-based chemotherapy plus paclitaxel.  
Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix.  
The patient’s Gynaecologic Oncology Group (GOG) performance status and body weight must be documented in the patient’s medical records at the time the treatment cycle is initiated.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10120P</td>
<td>900 mg</td>
<td>5</td>
<td>..</td>
<td>*2900.15</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>
Authority required (STREAMLINED)

6353

Advanced carcinoma of cervix

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease, AND
- The treatment must be in combination with platinum-based chemotherapy plus paclitaxel.

Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix.

Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1800 mg</td>
<td>7</td>
<td>..</td>
<td>*5673.89</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer
- Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
- Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

BEVACIZUMAB

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
- Services Australia
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

Authority required

Relapsed or recurrent glioblastoma

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have confirmed glioblastoma, AND
- Patient must have radiologic evidence of evaluable disease, AND
- Patient must have evidence of symptomatic progression, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, temozolomide, AND
- Patient must not receive more than 8 weeks of treatment per initial treatment course authorised under this restriction, AND
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, AND
- Patient must not have received prior treatment with this drug for this condition, AND
- The treatment must not exceed a dose of 10 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 15 mg per kg every 3 weeks.

The authority application must be made in writing and must include:
1. a completed authority prescription form;
2. a completed Glioblastoma PBS Authority Application - Supporting Information Form, which includes the following:
   a. evidence of confirmed glioblastoma confirmed by radiology report; and
   b. confirmation that the patient has failed to achieve an adequate response to, or is intolerant to, temozolomide.

Symptomatic progression is defined as:
1. Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; OR
2. Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema.

Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1800 mg</td>
<td>3</td>
<td>..</td>
<td>*5673.89</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer
- Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
- Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

BEVACIZUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

9346

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment 1

Treatment criteria:
• Patient must be undergoing combination treatment with atezolizumab and platinum-doublet chemotherapy.

Clinical criteria:
• The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
• Patient must not have previously been treated for this condition in the metastatic setting, AND
• Patient must have a WHO performance status of 0 or 1, AND
• The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

Authority required (STREAMLINED)

9347
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment 2

Treatment criteria:
• Patient must be undergoing combination treatment with atezolizumab and platinum-doublet chemotherapy.

Clinical criteria:
• The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
• Patient must have a WHO performance status of 0 or 1, AND
• Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, AND
• Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI), AND
• Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.

### BEVACIZUMAB

Note: Special Pricing Arrangements apply.

Authority required
Relapsed or recurrent glioblastoma
Treatment Phase: Grandfathering treatment

Clinical criteria:
• Patient must have confirmed glioblastoma, AND
• Patient must have had radiologic evidence of evaluable disease at the time non-PBS subsidised treatment with this drug for this condition was initiated, AND
• Patient must have had evidence of symptomatic progression at the time non-PBS subsidised treatment with this drug for this condition was initiated, AND
• Patient must have failed to achieve an adequate response to, or be intolerant to, temozolomide, AND
• Patient must have been receiving non-PBS subsidised treatment with this drug for this condition prior to 1 August 2019, AND
• Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less at the time non-PBS subsidised treatment with this drug for this condition was initiated, AND
• Patient must not have developed further symptomatic progression while being treated with this drug for this condition, AND
• The treatment must not exceed a dose of 10 mg per kg every 2 weeks; OR
• The treatment must not exceed a dose of 15 mg per kg every 3 weeks.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

The authority application must be made in writing and must include:
(1) a completed authority prescription form;
(2) a completed Glioblastoma PBS Authority Application - Supporting Information Form, which includes the following:
(a) evidence of confirmed glioblastoma confirmed by radiology report; and
(b) confirmation that the patient has failed to achieve an adequate response to, or is intolerant to, temozolomide.

Symptomatic progression is defined as:
i) Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; OR
ii) Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema.

Note: Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
**Relapsed or recurrent glioblastoma**  
**Treatment Phase:** Continuing treatment  

**Clinical criteria:**  
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**  
- Patient must not have developed further symptomatic progression while being treated with this drug for this condition, **AND**  
- The treatment must not exceed a dose of 10 mg per kg every 2 weeks; **OR**  
- The treatment must not exceed a dose of 15 mg per kg every 3 weeks.  

Symptomatic progression is defined as:  
1. Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; **OR**  
2. Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema.  

**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).  

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11731K</td>
<td>1800 mg</td>
<td>5</td>
<td>..</td>
<td>*5673.89</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

**BEVACIZUMAB**  
**Note** No increase in the maximum number of repeats may be authorised.  
**Note** Special Pricing Arrangements apply.  

**Stage IV (metastatic) non-small cell lung cancer (NSCLC)**  
**Treatment Phase:** Continuing treatment  

**Clinical criteria:**  
- Patient must be undergoing combination treatment with atezolizumab until disease progression, unless not tolerated.  
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**  
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**  
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.  

**Authority required (STREAMLINED)**  
9566  
Stage IV (metastatic) non-small cell lung cancer (NSCLC)  
**Treatment Phase:** Grandfathering treatment  

**Clinical criteria:**  
- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.  
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**  
- Patient must have previously received treatment with these drugs for this condition prior to 1 October 2019, **AND**  
- Patient must have stable or responding disease, **AND**  
- Patient must have a WHO performance status of 0 or 1.  

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a ‘Grandfathered’ patient must qualify under the ‘Continuing treatment’ criteria.  

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11811P</td>
<td>1800 mg</td>
<td>7</td>
<td>..</td>
<td>*5673.89</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

**BEVACIZUMAB**  
**Caution** The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.  
**Note** No increase in the maximum amount or number of units may be authorised.  
**Note** No increase in the maximum number of repeats may be authorised.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10959**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Concurrent use with atezolizumab in hepatocellular carcinoma

**Treatment criteria:**
- Patient must be undergoing combination treatment with PBS-subsidised atezolizumab for this PBS indication.

**Injection 12166H**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1800 mg</td>
<td>8</td>
<td>..</td>
<td>$5673.89</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

**BEVACIZUMAB**

**Authority required (STREAMLINED)**

**4594**

Metastatic colorectal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be previously untreated, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The treatment must be in combination with first-line chemotherapy, AND
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

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

**Authority required (STREAMLINED)**

**4587**

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition, AND
- Patient must not have progressive disease, AND
- The treatment must be in combination with first-line chemotherapy, AND
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

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

**Authority required (STREAMLINED)**

**4939**

Metastatic colorectal cancer

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have RAS wild-type metastatic colorectal cancer, AND
- Patient must be previously treated with PBS-subsidised first-line anti-EGFR antibodies, AND
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The treatment must be in combination with second-line chemotherapy, AND
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

Note This drug is not PBS-subsidised for use in combination with an anti-EGFR antibody.

**Authority required (STREAMLINED)**

**4968**

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease, AND
- The treatment must be in combination with second-line chemotherapy, AND
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

Note This drug is not PBS-subsidised for use in combination with an anti-EGFR antibody.

Note Bevacizumab is not PBS-subsidised when chemotherapy partners are switched whilst maintaining a bevacizumab backbone in the face of progressive disease.

Note The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.
### BLINATUMOMAB

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

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

**Note** Special Pricing Arrangements apply.

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

#### Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- The condition must not be present in the central nervous system or testis, **AND**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- Patient must not have received blinatumomab previously for the treatment of minimal residual disease; **OR**
- Patient must have had a relapse-free period of at least six months following completion of treatment with blinatumomab for minimal residual disease, **AND**
- The condition must have more than 5% blasts in bone marrow, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.

Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and
4. if applicable, the date of completion of blinatumomab treatment for minimal residual disease and the date of the patient's subsequent relapse; and
5. the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.

---

### Injection 7243F

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>900 mg</td>
<td>11</td>
<td>..</td>
<td>*2900.15</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

---

### Injection 11116C

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>651 mcg</td>
<td>..</td>
<td>..</td>
<td>*70816.97</td>
<td>41.00</td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

---

### BLINATUMOMAB

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

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

**Note** Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Acute lymphoblastic leukaemia

**Clinical criteria:**

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- The condition must not be present in the central nervous system or testis, **AND**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

### Injections

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>784 mcg</td>
<td>..</td>
<td>..</td>
<td>*82598.73 41.00</td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack)</td>
<td></td>
</tr>
</tbody>
</table>

### BLINATUMOMAB

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

**Note** Special Pricing Arrangements apply.

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microlitre, and absolute neutrophil count (ANC) of greater than 1,000 per microlitre.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microlitre, and absolute neutrophil count (ANC) of greater than 500 per microlitre.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum number of repeats will be authorised for completion of induction therapy.

**Note** An increase in maximum number of repeats of up to 2 will be allowed for completion of consolidation therapy.

**Authority required**

Acute lymphoblastic leukaemia

**Clinical criteria:**

- Patient must have a documented history of relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- Patient must have a documented history of receiving intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- Patient must have a documented history of more than 5% blasts in bone marrow, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 October 2019, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained through a request for an increased maximum amount, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.

Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

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

Treatment with this drug for this condition must not exceed 5 treatment cycles in a lifetime.

Patients who have received up to 2 treatment cycles as induction therapy with this drug for this condition prior to 1 October 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.
Patients who have received at least 1 treatment cycle as consolidation therapy with this drug for this condition prior to 1 October 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug. Patients who fail to demonstrate a complete remission (CR) or complete remission with incomplete haematological recovery (CRi) after 2 cycles of PBS-subsidised treatment with this agent must cease PBS-subsidised treatment with this agent. The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. date of the most recent blinatumomab dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised blinatumomab will be required for completion of induction or consolidation therapy; and
4. date of most recent chemotherapy prior to receiving non-PBS subsidised blinatumomab, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and
5. a copy of the most recent bone marrow biopsy report prior to receiving non-PBS subsidised blinatumomab.

### BLINATUMOMAB

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

**Authority required**

**Acute lymphoblastic leukaemia**

**Treatment Phase: Consolidation treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised induction treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission; OR
- Patient must have achieved a complete remission with partial haematological recovery, **AND**
- The treatment must not be more than 3 treatment cycles under this restriction in a lifetime, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>651 mcg</td>
<td></td>
<td>*70816.97</td>
<td>41.00</td>
<td></td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

**Authority required**

**Acute lymphoblastic leukaemia**

**Treatment Phase: Initial treatment of minimal residual disease of Pre-B-cell ALL**

**Treatment criteria:**
- Must be treated by a physician experienced in the treatment of haematological malignancies.

**Clinical criteria:**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be present in the central nervous system or testis, **AND**
• Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy, AND
• Patient must have minimal residual disease defined as at least $10^{-4}$ (0.01%) blasts based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL or as subsequent salvage therapy, whichever was the later, and measured using polymerase chain reaction or flow cytometry, AND
• The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.

For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.

Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Minimal residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and
(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application

 Patients who fail to demonstrate a response to PBS-subsidised treatment with this drug for this condition, are required must cease PBS-subsidised therapy with this agent.

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

**Authority required**

Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Treatment Phase: Continuing treatment of previously detectable minimal residual disease of Pre-B-cell ALL

**Treatment criteria:**

Must be treated by a physician experienced in the treatment of haematological malignancies.

**Clinical criteria:**

• Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, AND
• Patient must have achieved a complete remission, AND
• Patient must be minimal residual disease negative, defined as either undetectable using the same method used to determine original eligibility or less than $10^{-4}$ (0.01%) blasts based on measurement in bone marrow, AND
• Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, AND
• The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.

Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this drug at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

---

### BRENTUXIMAB VEDOTIN

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

• Patient must not have progressive disease, AND
• Patient must have previously been issued with an authority prescription for this drug.
The treatment must not exceed a lifetime total of 16 cycles.

**Injection 10180T**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>*19007.09</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**BRENTUXIMAB VEDOTIN**

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

**Authority required**
CD30 positive systemic anaplastic large cell lymphoma
Treatment Phase: Initial treatment

**Clinical criteria:**
• The treatment must be for curative intent, AND
• Patient must have undergone appropriate prior front-line curative intent chemotherapy, AND
• Patient must demonstrate relapsed or chemotherapy-refractory disease.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Systemic anaplastic large cell lymphoma Brentuximab PBS Authority Application - Supporting Information Form which includes the following:
(i) a histology report including evidence of the tumour’s CD30 positivity;
(ii) The date of initial diagnosis of systemic anaplastic large cell lymphoma;
(iii) Dates of commencement and completion of front-line curative intent chemotherapy; and
(iv) a declaration of whether the patient’s disease is relapsed or refractory, and the date and means by which the patient’s disease was assessed as being relapsed or refractory.

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

**Injection 10172J**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>3</td>
<td>..</td>
<td>*19007.09</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**BRENTUXIMAB VEDOTIN**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Note Special Pricing Arrangements apply.

**Authority required**
Relapsed or Refractory Hodgkin lymphoma
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition, AND
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, AND
• Patient must not receive more than 12 cycles of treatment under this restriction.

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

**Injection 11067L**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>*19007.09</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**BRENTUXIMAB VEDOTIN**

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition, **AND**
- Patient must not be suitable for ASCT for this condition; **OR**
- Patient must not be suitable for treatment with multi-agent chemotherapy for this condition, **AND**
- Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; **OR**
- Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition, **AND**
- Patient must not receive more than 4 cycles of treatment under this restriction.

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

(a) a completed authority prescription form; and
(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>3</td>
<td>..</td>
<td>*19007.09 41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
<td></td>
</tr>
</tbody>
</table>

**BRENTUXIMAB VEDOTIN**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition, **AND**
- Patient must not be suitable for ASCT for this condition; **OR**
- Patient must not be suitable for treatment with multi-agent chemotherapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 12 cycles of treatment under this restriction.

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

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>*19007.09 41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
<td></td>
</tr>
</tbody>
</table>

**BRENTUXIMAB VEDOTIN**

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional


### Authority required

Relapsed or Refractory Hodgkin lymphoma

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have undergone a primary autologous stem cell transplant (ASCT), **AND**
- Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; **OR**
- Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT, **AND**
- Patient must not receive more than 4 cycles of treatment under this restriction.

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

(a) a completed authority prescription form; and

(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11089P</td>
<td>200 mg</td>
<td>3</td>
<td>..</td>
<td>*19007.09</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

---

### BRENTUXIMAB VEDOTIN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

CD30 positive cutaneous T-cell lymphoma

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma, **AND**
- Patient must have CD30 positivity of at least 3% of malignant cells, **AND**
- Patient must have a diagnosis of mycosis fungoides; **OR**
- Patient must have a diagnosis of Sezary syndrome; **OR**
- Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma, **AND**
- Patient must have received prior systemic treatment for this condition, **AND**
- The condition must be relapsed or refractory, **AND**
- The treatment must not exceed 4 cycles under this restriction, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

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

(a) a completed authority prescription form; and

(b) a completed Cutaneous T-cell lymphoma (CTCL) Brentuximab vedotin PBS Authority Application Supporting Information Form which includes the following:

(i) Evidence of a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and

(ii) Evidence of CD30 positivity of at least 3% of malignant cells, either from a histology report on the tumour sample or from a flow cytometric analysis of lymphoma cells of the blood; and

(iii) Date of commencement and completion of the most recent prior systemic treatment.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11651F</td>
<td>180 mg</td>
<td>3</td>
<td>..</td>
<td>*19007.09</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

---

### BRENTUXIMAB VEDOTIN

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

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

**Note** Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
CD30 positive cutaneous T-cell lymphoma
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must have achieved an objective response with this drug, AND
• Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, AND
• The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, AND
• The treatment must not exceed 12 cycles under this restriction.

An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria. The treatment must not exceed a lifetime total of 16 cycles.

Injection

11661R

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>180 mg</td>
<td>11</td>
<td>..</td>
<td>19007.09</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

CETUXIMAB

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.

Authority required (STREAMLINED)
4788
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx
Treatment Phase: Continuing treatment
Clinical criteria:
• The treatment must be in combination with radiotherapy, AND
• Patient must be unable to tolerate cisplatin; OR
• Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Injection

7240C

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>550 mg</td>
<td>5</td>
<td>..</td>
<td>1900.24</td>
<td>41.00</td>
<td>Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

CETUXIMAB

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

Authority required (STREAMLINED)
4794
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx
Treatment Phase: Initial treatment
Clinical criteria:
• The treatment must be for the week prior to radiotherapy, AND
• Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Authority required (STREAMLINED)
4785
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx
Treatment Phase: Initial treatment
Clinical criteria:
• The treatment must be in combination with radiotherapy, AND
• Patient must be unable to tolerate cisplatin.

Injection

7223E

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>880 mg</td>
<td>..</td>
<td>..</td>
<td>2787.16</td>
<td>41.00</td>
<td>Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

CETUXIMAB

Note Special Pricing Arrangements apply.
Note This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

Authority required (STREAMLINED)
4965
**Metastatic colorectal cancer**  
**Treatment Phase: Initial treatment**  

**Clinical criteria:**  
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**  
- Patient must have a WHO performance status of 2 or less, **AND**  
- The condition must have failed to respond to first-line chemotherapy, **AND**  
- The treatment must be as monotherapy; **OR**  
- The treatment must be in combination with chemotherapy, **AND**  
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.  
Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab.

**Authority required (STREAMLINED) 4908**  
**Metastatic colorectal cancer**  
**Treatment Phase: Initial treatment**  

**Clinical criteria:**  
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**  
- Patient must have a WHO performance status of 0 or 1, **AND**  
- The condition must be previously untreated, **AND**  
- The treatment must be in combination with first-line chemotherapy, **AND**  
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

- **CETUXIMAB**
  - **Note** Special Pricing Arrangements apply.
  - **Note** This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.
  - **Note** This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.
  - **Note** The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.

**Authority required (STREAMLINED) 4912**  
**Metastatic colorectal cancer**  
**Treatment Phase: Continuing treatment**  

**Clinical criteria:**  
- Patient must have received an initial authority prescription for this drug for first-line treatment of RAS wild-type metastatic colorectal cancer, **AND**  
- Patient must not have progressive disease, **AND**  
- The treatment must be in combination with first-line chemotherapy, **AND**  
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

- **CETUXIMAB**
  - **Note** Special Pricing Arrangements apply.
  - **Note** This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.
  - **Note** This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.
  - **Note** The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.

**Authority required (STREAMLINED) 4945**  
**Metastatic colorectal cancer**  
**Treatment Phase: Continuing treatment**  

**Clinical criteria:**
• Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy, **AND**
• Patient must not have progressive disease, **AND**
• The treatment must be as monotherapy; **OR**
• The treatment must be in combination with chemotherapy, **AND**
• The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

### DURVALUMAB

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10126**

Unresectable Stage III non-small cell lung cancer

**Treatment Phase: Initial treatment**

**Clinical criteria:**
• Patient must have received platinum based chemoradiation therapy, **AND**
• The condition must not have progressed following platinum based chemoradiation therapy, **AND**
• Patient must have a WHO performance status of 0 or 1, **AND**
• Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

**Authority required (STREAMLINED)**

**10145**

Unresectable Stage III non-small cell lung cancer

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
• The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
• The treatment must not exceed 12 months in total for this condition under the initial, grandfathering or this continuing restriction combined, **AND**
• The treatment must be once in a lifetime with this drug for this condition.

**Authority required (STREAMLINED)**

**10174**

Unresectable Stage III non-small cell lung cancer

**Treatment Phase: Grandfather treatment**

**Clinical criteria:**
• Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2020, **AND**
• Patient must have received platinum based chemoradiation therapy prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
• The condition must not have progressed following platinum based chemoradiation therapy, **AND**
• Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
• The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

### INOTUZUMAB OZOGAMICIN

**Caution** Careful monitoring of patients is required due to risk of developing hepatotoxicity, including life-threatening hepatic veno-occlusive disease, and the increased risk of post-haematopoietic stem cell transplant non-relapse mortality observed in patients treated with inotuzumab.

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

**Note** No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

Note A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

Note Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

### Authority required

**Acute lymphoblastic leukaemia**

**Treatment Phase: Consolidation treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised induction treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission; **OR**
- Patient must have achieved a complete remission with partial haematological recovery, **AND**
- The treatment must not be more than 5 treatment cycles under this restriction in a lifetime, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

The treatment must not exceed 0.5mg per m² for all doses within a treatment cycle.

Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.

### INOTUZUMAB OZOGAMICIN

**Caution** Careful monitoring of patients is required due to risk of developing hepatotoxicity, including life-threatening hepatic veno-occlusive disease, and the increased risk of post-haematopoietic stem cell transplant non-relapse mortality observed in patients treated with inotuzumab.

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeat prescriptions may be authorised.
- **Note** Special Pricing Arrangements apply.
- **Note** Patients are eligible to receive a loading dose for the first dose of a treatment cycle while receiving induction treatment. Two prescriptions are required, the first prescription for the loading dose at a dose no higher than 0.8mg per m², and the second prescription for two doses at a dose no higher than 0.5mg per m². Both prescriptions must be submitted with the initial application.
- **Note** Once a patient achieves complete remission or complete remission with partial haematological recovery, a new prescription must be written under the consolidation treatment phase.
- **Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.
- **Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.
- **Note** Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Acute lymphoblastic leukaemia**

**Treatment Phase: Induction treatment**

**Clinical criteria:**
- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- The condition must be CD22-positive, **AND**
- The condition must have more than 5% blasts in bone marrow, **AND**
- The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.

This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

The authority application must be made in writing and must include:
1. two completed authority prescription forms;
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. evidence that the condition is CD22-positive; and
4. date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and
5. a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

The treatment must not exceed 0.8mg per m² for the first dose of a treatment cycle (Day 1), and 0.5mg per m² for subsequent doses (Days 8 and 15) within a treatment cycle.

Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.

### IPILIMUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

### Authority required (STREAMLINED)

#### 8555

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**
- The condition must not have previously been treated, **AND**
- The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.

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

### Injection 11644W

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mg</td>
<td>3</td>
<td>..</td>
<td>*17240.45</td>
<td>41.00</td>
<td>Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)</td>
</tr>
</tbody>
</table>

**IPILIMUMAB**

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

**Note** Special Pricing Arrangements apply.
**Authority required (STREAMLINED)**

**6585**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Re-induction treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction), **AND**
- The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

An initial objective response to treatment is defined as either:

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

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

**Caution**

Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

**Authority required (STREAMLINED)**

**10122**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, **AND**
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.

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

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

**Injection**

**2638W**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>360 mg</td>
<td>3</td>
<td>..</td>
<td>*45763.85</td>
<td>41.00</td>
<td>Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)</td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10117**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have stable or responding disease.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

**Injection**

**11152Y**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>*10234.35</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9299**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Chemotherapy items for Private Hospital use

- Patient must not have developed disease progression while being treated with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### Injection 1157F

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>10234.35</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

#### NIVOLUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

9252

Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have stable or responding disease, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### Injection 11425H

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>10234.35</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

#### NIVOLUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

9321

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**

- Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition, AND
- The treatment must be as monotherapy for this condition, AND
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

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

### Injection 11626X

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>10234.35</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

#### NIVOLUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

9298

Unresectable Stage III or Stage IV malignant melanoma

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have stable or responding disease.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

**Authority required (STREAMLINED)**

9214

Unresectable Stage III or Stage IV malignant melanoma

**Clinical criteria:**
• Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition, **AND**
• The treatment must be as monotherapy for this condition, **AND**
• Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

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

### NIVOLUMAB

- **Note**: No increase in the maximum number of repeats may be authorised.
- **Note**: Special Pricing Arrangements apply.
- **Note**: In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

#### Authority required (STREAMLINED) 10155

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, **AND**
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIIB, IIIIC, IIID or IV melanoma, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### NIVOLUMAB

- **Note**: No increase in the maximum number of repeats may be authorised.
- **Note**: Special Pricing Arrangements apply.
- **Note**: In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

#### Authority required (STREAMLINED) 10165

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must have progressed on or after prior platinum based chemotherapy.

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

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.
Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have a WHO performance status of 0 or 1, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, AND
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition.

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

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>11434T</td>
<td>480 mg</td>
<td>8</td>
<td>..</td>
<td>*10234.35</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer:
- Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)
- Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial Treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have a WHO performance status of 2 or less, AND
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; OR
- Patient must have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, AND
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.

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

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>11159H</td>
<td>480 mg</td>
<td>8</td>
<td>..</td>
<td>*10234.35</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer:
- Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)
- Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIIB, IIIIC, IIID or IV melanoma, AND
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, AND
- The condition must not be ocular or uveal melanoma, AND
The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

**Authority required (STREAMLINED)**

**10156**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathered patients treated with nivolumab as first-line therapy in unresectable Stage III or Stage IV malignant melanoma prior to 1 March 2020

**Clinical criteria:**
- Patient must have received non-PBS-subsidised supply of this drug as first-line therapy for unresectable Stage III or Stage IV malignant melanoma prior to 1 March 2020, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition. A patient may qualify for PBS-subsidised treatment under this restriction only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.
- Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

<table>
<thead>
<tr>
<th>Injection</th>
<th>11532Y</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA $</th>
<th>MRSVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mg</td>
<td>3</td>
<td>*2653.40</td>
<td>41.00</td>
<td>Opdive [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11627Y</td>
<td>360 mg</td>
<td>*7707.37</td>
<td>41.00</td>
<td>Opdive [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

**8573**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

**Clinical criteria:**
- The condition must not have previously been treated, **AND**
- The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

<table>
<thead>
<tr>
<th>Injection</th>
<th>11627Y</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA $</th>
<th>MRSVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>360 mg</td>
<td>3</td>
<td>*7707.37</td>
<td>41.00</td>
<td>Opdive [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be adjuvant to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required**
Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

**Authority required**

Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma
Treatment Phase: Grandfather treatment

Clinical criteria:
- Patient must have previously received non-PBS-subsidised drug for adjuvant treatment following complete surgical resection prior to 1 March 2020, **AND**
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

### Injection 11906P

Max. Amount | No. of Rpts | Premium $ | DPMA $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
480 mg | 5 | .. | *10234.35 | 41.00 | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

| Brand Name and Manufacturer
--- | --- |
| Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

**OBINUTUZUMAB**

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

Note: Special Pricing Arrangements apply.

**Authority required**

Stage II bulky or Stage III/IV follicular lymphoma
Treatment Phase: Maintenance therapy

Clinical criteria:
- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated initial restriction; **OR**
- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated grandfather restriction, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

### Injection 11455X

Max. Amount | No. of Rpts | Premium $ | DPMA $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1000 mg | 5 | .. | *5493.51 | 41.00 | Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

**OBINUTUZUMAB**

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

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

Note: Special Pricing Arrangements apply.

**Authority required**

Follicular lymphoma
Treatment Phase: Maintenance therapy

Clinical criteria:
- Patient must have previously received PBS subsidised treatment with this drug under the rituximab refractory initial restriction; OR
- Patient must have previously received PBS subsidised treatment with this drug under the rituximab refractory grandfather restriction, AND
- The condition must be CD20 positive, AND
- The condition must have been refractory to treatment with rituximab, AND
- Patient must have demonstrated a partial or complete response to PBS subsidised re-induction treatment with this drug for this condition, AND
- The treatment must be maintenance therapy, AND
- The treatment must be the sole PBS subsidised treatment for this condition, AND
- The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, AND
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

### OBINUTUZUMAB

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Induction treatment

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, AND
- The condition must be CD20 positive, AND
- The condition must have been untreated prior to initiating non-PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition. A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:
  - i) the previously untreated induction treatment restriction; or
  - ii) the rituximab-refractory re-induction restriction; or
  - iii) the previously untreated grandfather restriction; or
  - iv) the rituximab-refractory grandfather restriction.

#### Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Grandfather treatment - previously untreated setting

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, AND
- The condition must be CD20 positive, AND
- The condition must have been untreated prior to initiating non-PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition; OR
- Patient must have demonstrated a partial or complete response to induction treatment with this drug for this condition for maintenance treatment, AND
- The treatment must be the sole PBS subsidised treatment for maintenance treatment; AND
- The treatment must not exceed 12 doses or 2 years duration of maintenance treatment, whichever comes first. A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:
  - i) the previously untreated induction treatment restriction; or
  - ii) the rituximab-refractory re-induction restriction; or
  - iii) the previously untreated grandfather restriction; or
  - iv) the rituximab-refractory grandfather restriction.

### OBINUTUZUMAB

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

**Note** No increase in the maximum number of repeats may be authorised.
**Follicular lymphoma**

**Treatment Phase: Re-induction treatment**

**Clinical criteria:**
- Patient must not have previously received PBS subsidised obinutuzumab, **AND**
- The condition must be CD20 positive, **AND**
- The condition must be refractory to treatment with rituximab for this condition, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for re-induction treatment purposes only, **AND**
- The treatment must be in combination with bendamustine, **AND**
- The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition.

The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:
- i) the previously untreated induction treatment restriction; or
- ii) the rituximab-refractory re-induction restriction; or
- iii) the previously untreated grandfather restriction; or
- iv) the rituximab-refractory grandfather restriction.

**Authority required**

**Follicular lymphoma**

**Treatment Phase: Grandfather treatment - rituximab refractory**

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, **AND**
- The condition must be CD20 positive, **AND**
- The condition must have been refractory to treatment with rituximab prior to initiating non-PBS treatment this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be in combination with bendamustine for re-induction treatment, **AND**
- The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition; OR
- Patient must have demonstrated a partial or complete response to re-induction treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for maintenance treatment; AND
- The treatment must not exceed 12 doses or 2 years duration of maintenance treatment, whichever comes first.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:
- i) the previously untreated induction treatment restriction; or
- ii) the rituximab-refractory re-induction restriction; or
- iii) the previously untreated grandfather restriction; or
- iv) the rituximab-refractory grandfather restriction.

**Injection**

**Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>7</td>
<td>..</td>
<td>*5493.51</td>
<td>41.00</td>
<td>Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)</td>
</tr>
</tbody>
</table>

**Note** Obinutuzumab is not to be used as monotherapy or in combination with anti-cancer drugs other than chlorambucil under this restriction. For use with venetoclax, refer to the separate listing for this purpose.
Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

11052
Chronic lymphocytic leukaemia (CLL)
Treatment Phase: Combination use with chlorambucil only

**Clinical criteria:**
- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- Patient must be inappropriate for fludarabine based chemo-immunotherapy, **AND**
- The treatment must be in combination with chlorambucil, **AND**
- Patient must have a creatinine clearance 30 mL/min or greater, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); OR
- Patient must have a creatinine clearance less than 70 mL/min.

Treatment must be discontinued in patients who experience disease progression whilst on this treatment.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10418H</td>
<td>1000 mg</td>
<td>7</td>
<td>..</td>
<td>*5493.51</td>
<td>41.00</td>
<td>Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)</td>
</tr>
</tbody>
</table>

**PANITUMUMAB**

Note This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

**Authority required (STREAMLINED)**

5439
Metastatic colorectal cancer
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have failed to respond to first-line chemotherapy, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

**Authority required (STREAMLINED)**

5447
Metastatic colorectal cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

Note This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.

Note The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient’s lifetime.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10069Y</td>
<td>720 mg</td>
<td>5</td>
<td>..</td>
<td>*3972.49</td>
<td>41.00</td>
<td>Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**PANITUMUMAB**

Note Special Pricing Arrangements apply.
Note Panitumumab is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

**Authority required (STREAMLINED)**

**5526**  
Metastatic colorectal cancer  
Treatment Phase: Initial Treatment  
Clinical criteria:  
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**  
- Patient must have a WHO performance status of 0 or 1, **AND**  
- The condition must be previously untreated, **AND**  
- The treatment must be in combination with first-line chemotherapy, **AND**  
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.  
Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.  
Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.

**Authority required (STREAMLINED)**

**5452**  
Metastatic colorectal cancer  
Treatment Phase: Continuing treatment  
Clinical criteria:  
- Patient must have received an initial authority prescription for panitumumab for first-line treatment of RAS wild-type metastatic colorectal cancer, **AND**  
- Patient must not have progressive disease, **AND**  
- The treatment must be in combination with first-line chemotherapy, **AND**  
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.  
Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.  
Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.  

**Note** This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.

**Note** The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient’s lifetime.

**Injection 10508C**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium($)</th>
<th>DPMA($)</th>
<th>MRVSN($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>720 mg</td>
<td>9</td>
<td></td>
<td>*3972.49</td>
<td>41.00</td>
<td>Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

**Note** No increase in the maximum number of repeats may be authorised.  
**Note** Special Pricing Arrangements apply.  
**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required (STREAMLINED)**

**10705**  
Unresectable Stage III or Stage IV malignant melanoma  
Treatment Phase: Continuing treatment - 3 weekly treatment regimen  
Clinical criteria:  
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**  
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**  
- Patient must have stable or responding disease.

**Injection 10424P**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium($)</th>
<th>DPMA($)</th>
<th>MRVSN($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>7</td>
<td></td>
<td>*8289.11</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

**Note** No increase in the maximum number of repeats may be authorised.  
**Note** Special Pricing Arrangements apply.  
**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required (STREAMLINED)**

**10701**  
Unresectable Stage III or Stage IV malignant melanoma  
Treatment Phase: Continuing treatment - 6 weekly treatment regimen
Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have stable or responding disease.

**Injection 12123C**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg</td>
<td>3</td>
<td>..</td>
<td>16451.81</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED) 10696**
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must not exceed a total of 6 doses under this restriction.

**Injection 10475H**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>5</td>
<td>..</td>
<td>8289.11</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED) 10689**
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must not exceed a total of 3 doses under this restriction.

**Injection 12122B**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg</td>
<td>2</td>
<td>..</td>
<td>16451.81</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

Note No increase in the maximum quantity or number of units may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

Authority required (STREAMLINED)
Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy; **OR**
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; **OR**
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required** (STREAMLINED)

Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

**Injection 11632F**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>*8289.11</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; **OR**
- Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition, **AND**
- Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

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

(a) a completed authority prescription form;
(b) a completed Hodgkin lymphoma pembrolizumab PBS Authority Application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
The treatment must not exceed a total of 35 cycles in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>8289.11</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

- **No** increase in the maximum quantity or number of units may be authorised.
- **No** increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.
- Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

### Authority required

Resected Stage III B, Stage IIIC or Stage IIID malignant melanoma

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be adjuvant to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

### Authority required

Resected Stage III B, Stage IIIC or Stage IIID malignant melanoma

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

### Authority required

Resected Stage III B, Stage IIIC or Stage IIID malignant melanoma

**Treatment Phase: Grandfather treatment**

**Clinical criteria:**
- Patient must have previously received non-PBS-subsidised drug for adjuvant treatment following complete surgical resection prior to 1 September 2020, **AND**
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, **AND**
- Patient must not have evidence of recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.
Clinical criteria:
- The treatment must be adjuvant to complete surgical resection, AND
- Patient must have a WHO performance status of 1 or less, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must not have received prior PBS-subsidised treatment for this condition, AND
- The treatment must commence within 12 weeks of complete resection, AND
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Authority required
Resected Stage III B, Stage IIC or Stage IIID malignant melanoma
Treatment Phase: Continuing treatment - 6 weekly treatment regimen
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection, AND
- Patient must not have experienced disease recurrence, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

Authority required
Resected Stage III B, Stage IIC or Stage IIID malignant melanoma
Treatment Phase: Grandfather treatment - 6 weekly treatment regimen
Clinical criteria:
- Patient must have previously received non-PBS-subsidised drug for adjuvant treatment following complete surgical resection prior to 1 September 2020, AND
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, AND
- Patient must not have evidence of recurrence, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must not have received prior PBS-subsidised treatment for this condition, AND
- Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, AND
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

PEMBROLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

Authority required (STREAMLINED)
10681
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment - 3 weekly treatment regimen
Clinical criteria:
- Patient must not have previously been treated for this condition in the metastatic setting, AND
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, AND
- The treatment must not exceed a total of 7 doses under this restriction.

Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Authority required (STREAMLINED)
10682
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment - 3 weekly treatment regimen
Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have developed disease progression while being treated with this drug for this condition, AND
• The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

**Authority required (STREAMLINED)**

**10697**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfather treatment - 3 weekly treatment regimen

**Clinical criteria:**
• Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019, AND
• Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, AND
• Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS subsidised treatment with this drug for this condition, AND
• Patient must have stable or responding disease, AND
• Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, AND
• The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, AND
• The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once.

**Note** Following completion of the initial PBS subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11492W</td>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>*8289.11</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required (STREAMLINED)**

**10704**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment - 6 weekly treatment regimen

**Clinical criteria:**
• Patient must not have previously been treated for this condition in the metastatic setting, AND
• Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, AND
• Patient must have a WHO performance status of 0 or 1, AND
• The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, AND
• The treatment must not exceed a total of 4 doses under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

**10693**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment - 6 weekly treatment regimen

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have developed disease progression while being treated with this drug for this condition, AND
• The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under this restriction.

**Authority required (STREAMLINED)**

**10683**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfather treatment - 6 weekly treatment regimen
Clinic criteria:
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under this restriction.

**Note**
In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note**
A patient may only qualify for PBS-subsidised treatment under this restriction once.

**Note**
Following completion of the initial PBS subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>12121Y</td>
<td></td>
<td></td>
<td>400 mg</td>
<td>3</td>
<td>16451.81 41.00 Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

**Note**
No increase in the maximum amount or number of units may be authorised.

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

**Note**
Special Pricing Arrangements apply.

**Note**
Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**
Relapsed or refractory primary mediastinal B-cell lymphoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient's medical records, **AND**
- Patient must have been treated with rituximab-based chemotherapy for this condition, **AND**
- Patient must be experiencing relapsed/refractory disease, **AND**
- Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; OR
- Patient must have undergone an autologous stem cell transplant (ASCT); OR
- Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form;
(b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application, which includes:
(i) confirmation that histology results with PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient's medical records;
(ii) details of prior treatments for this condition.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Relapsed or refractory primary mediastinal B-cell lymphoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed a total of 35 cycles in a lifetime.

Note: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Relapsed or refractory primary mediastinal B-cell lymphoma

Treatment Phase: Grandfather treatment (initial treatment of a patient commenced on non-PBS-subsidised treatment)

Clinical criteria:
- Patient must have received treatment with this drug for this condition prior to 1 September 2020, AND
- The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient’s medical records, AND
- Patient must have been treated with rituximab-based chemotherapy prior to initiating treatment with this drug for this condition, AND
- Patient must have been experiencing relapsed/refractory disease prior to initiating treatment with this drug for this condition, AND
- Patient must have been autologous stem cell transplant (ASCT) ineligible following a single line of treatment prior to initiating treatment with this drug for this condition; OR
- Patient must have undergone an autologous stem cell transplant (ASCT) prior to initiating treatment with this drug for this condition; OR
- Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must have included rituximab-based chemotherapy, prior to initiating treatment with this drug for this condition, AND
- Patient must not have received treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition prior to initiating non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, AND
- The treatment must not exceed a total of 35 cycles in a lifetime, AND
- The treatment must not exceed a total of 7 doses under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form;
(b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application for Grandfathered patients, which includes:
(i) confirmation that histology results and PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient’s medical records;
(ii) details of prior treatments for this condition

Note: Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a ‘Grandfathered’ patient must qualify under the ‘Continuing treatment’ criteria.

Note: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note: Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>*8289.11</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

● PERTUZUMAB

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

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

Note: Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

**Treatment Phase**: Initial treatment

**Clinical criteria:**
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not have received prior anti-HER2 therapy for this condition, **AND**
- Patient must not have received prior chemotherapy for this condition, **AND**
- The treatment must be in combination with trastuzumab and a taxane, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH).

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

### Injection 10334X

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>840 mg</td>
<td>..</td>
<td>..</td>
<td>*6357.17</td>
<td>41.00</td>
<td>Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**PERTUZUMAB**

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

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

**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).

**Note** The criterion that limits breaks in treatment with pertuzumab under this restriction has been temporarily modified due to the current risk of COVID-19. This allows an extended break in therapy with PBS-subsidised pertuzumab in patients who are at risk of COVID-19.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

**Treatment Phase**: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be in combination with trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.
- A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
- The treatment must not exceed a lifetime total of one course. However, treatment breaks are permitted. A patient who has a treatment break in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

### Injection 10308M

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>420 mg</td>
<td>3</td>
<td>..</td>
<td>*3241.79</td>
<td>41.00</td>
<td>Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**RITUXIMAB**

**Authority required (STREAMLINED)**

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

**Treatment Phase**: Induction or re-induction therapy

**Clinical criteria:**
- The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
• The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
• The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, **AND**
• The treatment must be in combination with chemotherapy, **AND**
• Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia for induction course (including consolidation course).

<table>
<thead>
<tr>
<th>Injection</th>
<th>7257Y</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>7</td>
<td>..</td>
<td>*1703.67</td>
<td>41.00</td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

---

**RITUXIMAB**

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

**Authority required [STREAMLINED]**

10227

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

Treatment Phase: Re-induction therapy

**Clinical criteria:**

• The treatment must be for re-induction treatment purposes only, **AND**
• The condition must have relapsed or be refractory to treatment, **AND**
• Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

<table>
<thead>
<tr>
<th>Injection</th>
<th>11935E</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>3</td>
<td>..</td>
<td>*1703.67</td>
<td>41.00</td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

---

**RITUXIMAB**

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

**Authority required [STREAMLINED]**

9542

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

Treatment Phase: Maintenance therapy

**Clinical criteria:**

• The treatment must be maintenance therapy, **AND**
• Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current treatment with this drug for this condition, **AND**
• Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

<table>
<thead>
<tr>
<th>Injection</th>
<th>7258B</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>7</td>
<td>..</td>
<td>*1703.67</td>
<td>41.00</td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
</tbody>
</table>
**RITUXIMAB**

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

**Authority required (STREAMLINED)**

7399
Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must be in complete remission, **AND**
- Patient must not receive more than 6 doses in total under this restriction.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>7259C</td>
<td>800 mg</td>
<td>5</td>
<td>..</td>
<td>*1703.67</td>
<td>41.00</td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

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

**Authority required (STREAMLINED)**

9451
Stage III or IV CD20 positive follicular B-cell non-Hodgkin’s lymphoma

**Clinical criteria:**
- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin’s lymphoma, received immediately prior to this current treatment with this drug for this condition, **AND**
- Patient must not have received bendamustine induction therapy, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10193L</td>
<td>800 mg</td>
<td>11</td>
<td>..</td>
<td>*1703.67</td>
<td>41.00</td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB**

*Note* Increased maximum amounts can be requested where a patient’s weight is greater than 125 kg.

*Note* Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED)**

10296
Early HER2 positive breast cancer

**Clinical criteria:**
- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.
HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

### TRASTUZUMAB

**Note** Increased maximum quantity will be authorised where a patient requires a new loading dose due to a break in therapy of more than 1 week but less than 6 weeks from the last dose or a patient’s weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED)

**10213**

Early HER2 positive breast cancer

**Treatment Phase:** Continuing treatment (weekly regimen)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

### Injection 7264H

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 mg</td>
<td>..</td>
<td>*1720.17</td>
<td>41.00</td>
<td></td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### TRASTUZUMAB

**Note** Increased maximum quantity will be authorised where a patient requires a new loading dose due to a break in therapy of more than 1 week but less than 6 weeks from the last dose or a patient’s weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED)

**10294**

Early HER2 positive breast cancer

**Treatment Phase:** Continuing treatment (3 weekly regimen)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

### Injection 7265J

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>250 mg</td>
<td>9</td>
<td>*957.25</td>
<td>41.00</td>
<td></td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### Injection 7267L

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 mg</td>
<td>3</td>
<td>*2483.09</td>
<td>41.00</td>
<td></td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>
TRASTUZUMAB

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

Note: Increased maximum quantity will be authorised where a patient's weight is greater than 125 kg.

Note: Authority applications for increased quantities/repeats (where relevant) 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 (STREAMLINED)**

9349

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, a new loading dose may be required.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMA ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 mg</td>
<td>3</td>
<td>..</td>
<td>*2483.09</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

TRASTUZUMAB

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

Note: Increased maximum quantity will be authorised where a patient's weight is greater than 125 kg.

Note: Authority applications for increased quantities/repeats (where relevant) 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 (STREAMLINED)**

9353

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, AND
- The treatment must not be in combination with nab-paclitaxel, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMA ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>..</td>
<td>..</td>
<td>*3341.37</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

TRASTUZUMAB

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

Note: Increased maximum quantity will be authorised where a patient's weight is greater than 125 kg.

Note: Authority applications for increased quantities/repeats (where relevant) 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 (STREAMLINED)**

9573
Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction

TREATMENT PHASE: INITIAL TREATMENT

Clinical criteria:
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity as demonstrated by immunohistochemistry 2+ or more in tumour material, AND
- Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on more than 6 copies of HER2 in the same tumour tissue sample, AND
- Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on the ratio of HER2 to chromosome 17 being more than 2 in the same tumour tissue sample, AND
- Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; OR
- Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil, AND
- Patient must not have previously received this drug for this condition, AND
- Patient must not have received prior chemotherapy for this condition, AND
- Patient must have a WHO performance status of 2 or less, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

Injection 10589H

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>..</td>
<td>..</td>
<td>*3341.37</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

TRAStuzumab

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

Note: Increased maximum quantity will be authorised where a patient requires a new loading dose due to a break in therapy of more than 1 week but less than 6 weeks from the last dose or a patient's weight is greater than 125 kg.

Note: Authority applications for increased quantities/repeats (where relevant) 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).

Injection 10597R

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 mg</td>
<td>3</td>
<td>..</td>
<td>*2483.09</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

TRAStuzumab

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

Note: Increased maximum amounts can be requested where a patient's weight is greater than 125 kg.

Note: Authority applications for increased quantities/repeats (where relevant) 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).

Injection 10597R

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 mg</td>
<td>3</td>
<td>..</td>
<td>*2483.09</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>
• Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), AND
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND
• Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
• Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

<table>
<thead>
<tr>
<th>Injection</th>
<th>7266K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1000 mg</td>
<td>..</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### TRASTUZUMAB EMTANSINE

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Increased maximum amounts can be requested where a patient’s weight is greater than 125 kg.

**Authority required**
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, AND
- The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR
- The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The treatment must be as monotherapy, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:
(i) details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;
(ii) dates of treatment with trastuzumab and pertuzumab; and
(iii) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or
(iv) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer, AND
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND
• The treatment must be as monotherapy, **AND**
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

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

The treatment must not exceed a lifetime total of one continuous course for this PBS indication.

**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).

### Injection

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)</td>
</tr>
<tr>
<td>Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB EMTANSINE**

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

**Note** Increased maximum amounts can be requested where a patient’s weight is greater than 125 kg.

**Authority required**

Early HER2 positive breast cancer

**Treatment Phase:** Initial adjuvant treatment

**Clinical criteria:**

- The treatment must be prescribed within 12 weeks after surgery, **AND**
- Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report, **AND**
- Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.

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 details from the pathology report from an approved pathology authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Early HER2 positive breast cancer

**Treatment Phase:** Continuing adjuvant treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.

**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).

**Authority required**

Early HER2 positive breast cancer

**Treatment Phase:** Grandfather adjuvant treatment

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug as adjuvant treatment of early HER2 positive breast cancer prior to 1 April 2020, **AND**
- The treatment must have been prescribed within 12 weeks after surgery prior to commencing treatment with this drug, **AND**
• Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report, AND
• Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery, AND
• Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or symptomatic heart failure, AND
• The treatment must not extend beyond 42 weeks (14 cycles) duration using non-PBS-subsidised and PBS-subsidised drug supply obtained under the grandfather restriction and the continuing treatment restrictions combined.

Authority applications for grandfather 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 details from the pathology report from an approved pathology authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery and the number of non-PBS-subsidised cycles of treatment received by the patient.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Antineoplastic and Immunomodulating Agents**

### Injection 11956G

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>450 mg</td>
<td>6</td>
<td>..</td>
<td>*7790.09</td>
<td>41.00</td>
<td>Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### Other antineoplastic agents

#### Arsenic

**Authority required (STREAMLINED)**

6018
Acute promyelocytic leukaemia
Treatment Phase: Induction and consolidation treatment

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

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 mg</td>
<td>140</td>
<td>..</td>
<td>*620.23</td>
<td>41.00</td>
<td>Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)</td>
</tr>
</tbody>
</table>

#### Arsenic

**Authority required (STREAMLINED)**

4793
Acute promyelocytic leukaemia
Treatment Phase: Induction and consolidation treatment

Clinical criteria:
• The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript, AND
• The condition must be relapsed, AND
• Patient must be arsenic naive at induction.

**Authority required (STREAMLINED)**

5997
Acute promyelocytic leukaemia

Clinical criteria:
• The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript.
### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7962**

Multiple myeloma

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

**Clinical criteria:**

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, AND
- Patient must have previously received 8 treatment cycles of bortezomib for progressive disease, AND
- Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib, AND
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, AND
- Patient must not have a gap of more than 10 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition following completion of 8 treatment cycles, AND
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.

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 prescribing.

A response assessment prior to cycle 9 must be documented in the patient's medical records.

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

---

### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7960**

Multiple myeloma

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

**Clinical criteria:**

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, AND
- Patient must have previously received 8 treatment cycles of bortezomib in the current treatment course, AND
- Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib, AND
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, AND
- Patient must not have a gap of more than 10 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition following completion of 8 treatment cycles, AND
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.
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 prescribing.

A response assessment prior to cycle 9 must be documented in the patient's medical records.

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

### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

**Injection 7272R**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>11</td>
<td>..</td>
<td>*1400.09</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

---

**Authority required (STREAMLINED)**

**7940**

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and be ineligible for high dose chemotherapy, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved a best confirmed response to bortezomib at the time of prescribing, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide, **AND**
- Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

Continuing PBS-subsidised supply requires that the gap between the initial PBS-subsidised treatment with this drug for this condition and this continuing treatment is no more than 6 months.

**Authority required (STREAMLINED)**

**7941**

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for newly diagnosed symptomatic multiple myeloma, **AND**
- Patient must have severe acute renal failure, **AND**
- Patient must have demonstrated at least a partial response at the completion of cycle 4, **AND**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

A copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority and diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.

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

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

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

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

(a) at least a 50% reduction in bone marrow plasma cells; or
(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or
(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.
Continuing PBS-subsidised supply requires that the gap between the initial PBS-subsidised treatment with this drug for this condition and this continuing treatment is no more than 6 months.

**BORTEZOMIB**

**Note** The criterion that limits up to 4 cycles of treatment with bortezomib under this restriction has been temporarily removed due to the current risk of COVID-19. This allows continuity of treatment with PBS-subsidised bortezomib in those patients whose transplant may be delayed at this time.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10338**
Symptomatic multiple myeloma
Clinical criteria:
- Patient must be newly diagnosed, **AND**
- Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with chemotherapy.
Details of the histological diagnosis of multiple myeloma must be documented in the patient’s medical records.

**Injection 7274W**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>19</td>
<td>..</td>
<td>*1400.09</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 1 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**BORTEZOMIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7961**
Multiple myeloma
Treatment Phase: Treatment of Progressive disease - Initial PBS-subsidised treatment
Clinical criteria:
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.
Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in 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.
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 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 must be documented in the patient’s medical records.
Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient’s medical records:
(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
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(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 must 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) must be documented in the patient’s medical records. 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 documented in the patient’s medical records.

Authority required (STREAMLINED)
7974
Multiple myeloma

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

Clinical criteria:
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, AND
- Patient must have previously received 4 treatment cycles of bortezomib for progressive disease, AND
- Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib, AND
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, AND
- Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.

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 prescribing.

A response assessment prior to cycle 5 must be documented in the patient’s medical records. 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.

---

**Injection 7268M**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>15</td>
<td>..</td>
<td>1400.09</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

---

**BORTEZOMIB**

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
7938
Multiple myeloma

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

Clinical criteria:
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, AND
- Patient must have progressive disease, AND
- Patient must have previously been treated with PBS-subsidised bortezomib, AND
- Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy, AND
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, AND
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.
Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in 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.
Details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters that will be used to assess response, and diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously documented must be documented in the patient's medical records.
Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:
(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 must be used to determine response, results for either (a) or (b) or (c) must be documented in the patient's medical records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records.
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 documented in the patient's medical records.

Authority required (STREAMLINED)
7939
Multiple myeloma
Treatment Phase: Retreatment of Progressive disease - Continuing PBS-subsidised treatment
Clinical criteria:
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, AND
- Patient must have previously received 4 treatment cycles of bortezomib in the current treatment course, AND
- Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib, AND
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, AND
- Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.
Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.
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 prescribing.

A response assessment prior to cycle 5 must be documented in the patient's medical records.

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.

<table>
<thead>
<tr>
<th>Injection</th>
<th>7271Q</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>3000 mcg</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BORTEZOMIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10455**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- Patient must be ineligible for high dose chemotherapy, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

**Authority required (STREAMLINED)**

**10426**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- Patient must have severe acute renal failure, **AND**
- Patient must require dialysis; **OR**
- Patient must be at high risk of requiring dialysis in the opinion of a nephrologist, **AND**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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 must be documented in the patient's medical records. 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 documented in the patient's medical records 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 documented in the patient's medical records.

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 documented in the patient's medical records.
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.

**Authority required (STREAMLINED)**

**10454**

Multiple myeloma

Treatment Phase: Triple combination therapy (bortezomib, lenalidomide and dexamethasone)

**Clinical criteria:**

- The condition must be newly diagnosed, AND
- The treatment must be in combination with lenalidomide and dexamethasone, AND
- The treatment must not be in combination with PBS-subsidised thalidomide, pomalidomide or carfilzomib, AND
- The treatment must not be changing from dual combination therapy with lenalidomide and dexamethasone for symptomatic multiple myeloma to triple therapy with lenalidomide, bortezomib and dexamethasone, AND
- Patient must not receive more than 8 cycles of treatment with bortezomib under this restriction.

**Injection 7238Y**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>31</td>
<td>..</td>
<td>*1400.09</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 1 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**CARFILZOMIB**

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

*Note:* No increase in the maximum amount or number of units may be authorised.

*Note:* Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, AND
- The treatment must be in combination with dexamethasone, AND
- Patient must have progressive disease after at least one prior therapy, AND
- Patient must have undergone or be ineligible for a stem cell transplant, AND
- Patient must not have previously received this drug for this condition, AND
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, AND
- Patient must not receive more than three cycles of treatment 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 in 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.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be in combination with dexamethasone, AND
- Patient must not develop disease progression while receiving treatment with this drug for this condition, AND
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, AND
- Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised 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 in 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.

### Injection

**11230C**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mg</td>
<td>17</td>
<td>..</td>
<td>2699.81</td>
<td>41.00</td>
<td>Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**ERIBULIN**

**Note** A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.

**Authority required (STREAMLINED)**

**4649**

Locally advanced or metastatic breast cancer

**Clinical criteria:**
- Patient must have progressive disease, **AND**
- Patient must have failed at least two prior chemotherapeutic regimens for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Injection**

**10140Q**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mg</td>
<td>13</td>
<td>..</td>
<td>819.98</td>
<td>41.00</td>
<td>Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)</td>
</tr>
</tbody>
</table>

**ERIBULIN**

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

**Authority required (STREAMLINED)**

**7258**

Advanced (unresectable and/or metastatic) liposarcoma

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have an ECOG performance status of 2 or less, **AND**
- The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must be aged 18 years or older.

**Injection**

**11199K**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mg</td>
<td>7</td>
<td>..</td>
<td>819.98</td>
<td>41.00</td>
<td>Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)</td>
</tr>
</tbody>
</table>

**IRINOTECAN**

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

**Injection**

**7249M**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>11</td>
<td>..</td>
<td>192.17</td>
<td>41.00</td>
<td>Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)</td>
</tr>
</tbody>
</table>
### TOPOTECAN

#### Injection 7260D

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
| 3500 mcg    | 17          | ...       | *158.94| 41.00   | Hycamtin [SZ] (topotecan 4 mg injection, 5 vials)  
Topotecan Accord [OC] (topotecan 4 mg/4 mL injection, 5 x 4 mL vials) |
Chemotherapy items for Public Hospital use

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS ............................................................... 77

ANTINEOPLASTIC AGENTS ........................................................................................................... 77
ALKYLATING AGENTS ................................................................................................................ 77
ANTIMETABOLITES ..................................................................................................................... 78
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS ........................................ 80
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES .............................................. 82
OTHER ANTINEOPLASTIC AGENTS .......................................................................................... 84
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

BENDAMUSTINE

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

Authority required (STREAMLINED)

7972
Previously untreated stage III or IV mantle cell lymphoma
Treatment Phase: Induction treatment
Clinical criteria:
- The condition must be CD20 positive, **AND**
- The treatment must be in combination with rituximab, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction, **AND**
- Patient must not be eligible for stem cell transplantation.

Authority required (STREAMLINED)

7943
Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma
Treatment Phase: Induction treatment
Clinical criteria:
- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- The treatment must be in combination with rituximab or obinutuzumab, **AND**
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

Authority required (STREAMLINED)

7944
Follicular lymphoma
Treatment Phase: Re-induction treatment
Clinical criteria:
- The condition must be CD20 positive, **AND**
- The condition must be refractory to treatment with rituximab for this condition, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for re-induction treatment purposes only, **AND**
- The treatment must be in combination with obinutuzumab, **AND**
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10760H</td>
<td>200 mg</td>
<td>11</td>
<td></td>
<td>1700.42</td>
<td>41.00</td>
<td>Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4327R</td>
<td>2800 mg</td>
<td>17</td>
<td></td>
<td>157.48</td>
<td>41.00</td>
<td>Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Endoxan [BX] (cyclophosphamide 500 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>448D</td>
<td>4000 mg</td>
<td>19</td>
<td></td>
<td>282.42</td>
<td>41.00</td>
<td>Holoxan [BX] (ifosfamide 1 g injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Holoxan [BX] (ifosfamide 2 g injection, 1 vial)</td>
</tr>
</tbody>
</table>

Nitrosoureas
### FOTEMUSTINE

**Authority required (STREAMLINED)**

**6288**

Metastatic malignant melanoma

<table>
<thead>
<tr>
<th>Injection</th>
<th>4437M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>220 mg</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>8</td>
</tr>
<tr>
<td>Premium $</td>
<td>*1847.28</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td></td>
</tr>
<tr>
<td>Brand Name and Manufacturer</td>
<td>Muphoran [SE] (fotemustine 208 mg injection [1 vial] (&amp;) inert substance diluent [4 mL ampoule], 1 pack)</td>
</tr>
</tbody>
</table>

### ANTIMETABOLITES

**Folic acid analogues**

### METHOTREXATE

**Injection**

**4502Y**

| Max. Amount | 250 mg |
| No. of Rpts | 5 |
| Premium $ | *111.28 |
| DPMA $ | 41.00 |
| MRVSN $ | |
| Brand Name and Manufacturer | DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) |
| | DBL Methotrexate [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) |
| | DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) |
| | DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) |
| | Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) |
| | Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) |
| | Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial) |
| | Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) |
| | Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) |

### METHOTREXATE

**Restricted benefit**

Patients receiving treatment with a high dose regimen

<table>
<thead>
<tr>
<th>Injection</th>
<th>4512L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Amount</td>
<td>20000 mg</td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>..</td>
</tr>
<tr>
<td>Premium $</td>
<td>*839.18</td>
</tr>
<tr>
<td>DPMA $</td>
<td>41.00</td>
</tr>
<tr>
<td>MRVSN $</td>
<td></td>
</tr>
<tr>
<td>Brand Name and Manufacturer</td>
<td>DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td>DBL Methotrexate [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)</td>
</tr>
<tr>
<td></td>
<td>DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)</td>
</tr>
<tr>
<td></td>
<td>DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td>Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td>Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td>Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial)</td>
</tr>
<tr>
<td></td>
<td>Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td>Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)</td>
</tr>
</tbody>
</table>

### PEMETREXED

**Injection**

**4600D**

| Max. Amount | 1100 mg |
| No. of Rpts | 5 |
| Premium $ | *186.94 |
| DPMA $ | 41.00 |
| MRVSN $ | |
| Brand Name and Manufacturer | Alimta [LY] (pemetrexed 100 mg injection, 1 vial) |
| | Alimta [LY] (pemetrexed 500 mg injection, 1 vial) |
| | Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial) |
| | Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial) |
| | Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial) |
| | Pemetrexed APOTEX [TX] (pemetrexed 500 mg injection, 1 vial) |
Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial)
Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial)
Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial)
Reladdin [AF] (pemetrexed 100 mg injection, 1 vial)
Reladdin [AF] (pemetrexed 500 mg injection, 1 vial)
Tevatrexed [TB] (pemetrexed 100 mg injection, 1 vial)
Tevatrexed [TB] (pemetrexed 500 mg injection, 1 vial)

**PRA LATREXATE**

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

**Authority required**

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma
Treatment Phase: Continuing treatment

**Clinical criteria:**

- The condition must be relapsed or chemotherapy refractory, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11272G</td>
<td>80 mg</td>
<td>11</td>
<td>..</td>
<td>*4445.78</td>
<td>41.00</td>
<td>Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)</td>
</tr>
</tbody>
</table>

**PRA LATREXATE**

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

**Authority required**

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma
Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be relapsed or chemotherapy refractory, **AND**
- Patient must have undergone appropriate prior front-line curative intent chemotherapy.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11293J</td>
<td>80 mg</td>
<td>5</td>
<td>..</td>
<td>*4445.78</td>
<td>41.00</td>
<td>Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)</td>
</tr>
</tbody>
</table>

**RAL TITREXED**

**Authority required (STREAMLINED)**

6228
Advanced colorectal cancer

**Clinical criteria:**

- The treatment must only be used as a single agent in the treatment of this condition.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4610P</td>
<td>7 mg</td>
<td>8</td>
<td>..</td>
<td>*1128.62</td>
<td>41.00</td>
<td>Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**Purine analogues**

**CLADRIBINE**

**Authority required (STREAMLINED)**

6265
Hairy cell leukaemia

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4326Q</td>
<td>17 mg</td>
<td>6</td>
<td>..</td>
<td>*1126.22</td>
<td>41.00</td>
<td>Leustatin [JC] (cladribine 10 mg/10 mL injection, 10 mL vials) Litak [AF] (cladribine 10 mg/5 mL injection, 5 mL vials)</td>
</tr>
</tbody>
</table>

**FLUDARABINE**

**Note** Pharmaceutical benefits that have the form fludarabine phosphate 50 mg injection and pharmaceutical benefits that have the form fludarabine phosphate 50 mg/2 mL injection are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4393F</td>
<td>55 mg</td>
<td>29</td>
<td>..</td>
<td>*149.46</td>
<td>41.00</td>
<td>Fludarabine AMNEAL [JU] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)</td>
</tr>
</tbody>
</table>
### Pyrimidine analogues

<p>| CYTARABINE | Injection 4357H |</p>
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>7000 mg</td>
<td>15</td>
<td>..</td>
<td>*883.78</td>
<td>41.00</td>
<td>Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)</td>
</tr>
</tbody>
</table>

### FLUOROURACIL

<p>| FLUOROURACIL | Injection 4394G |</p>
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5500 mg</td>
<td>11</td>
<td>..</td>
<td>*124.78</td>
<td>41.00</td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

### FLUOROURACIL

<p>| FLUOROURACIL | Injection 4431F |</p>
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>23</td>
<td>..</td>
<td>*92.87</td>
<td>41.00</td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

### GEMCITABINE

<p>| GEMCITABINE | Injection 4439P |</p>
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mg</td>
<td>17</td>
<td>..</td>
<td>*148.83</td>
<td>41.00</td>
<td>DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)</td>
</tr>
</tbody>
</table>

### PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

| Vinca alkaloids and analogues |

Fludarabine Juno [JO] (fludarabine phosphate 50 mg injection, 1 vial)
### Antineoplastic and Immunomodulating Agents

#### Chemotherapy Items for Public Hospital Use

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Formulation</th>
<th>Maximum Dose</th>
<th>Number of Repeats</th>
<th>Premium ($)</th>
<th>DPMA ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vinblastine</strong></td>
<td>Injection 4618C</td>
<td>20 mg</td>
<td>17</td>
<td>..</td>
<td>*159.12</td>
<td>41.00</td>
<td>DBL Vinblastine [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)</td>
</tr>
<tr>
<td><strong>Vinblastine</strong></td>
<td>Injection 4619D</td>
<td>2 mg</td>
<td>7</td>
<td>..</td>
<td>*103.62</td>
<td>41.00</td>
<td>DBL Vincristine Sulfate [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)</td>
</tr>
<tr>
<td><strong>Vinorelbine</strong></td>
<td>Injection 4620E</td>
<td>70 mg</td>
<td>7</td>
<td>..</td>
<td>*156.68</td>
<td>41.00</td>
<td>Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial) Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td><strong>Podophyllotoxin Derivatives</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Etoposide</strong></td>
<td>Injection 4428C</td>
<td>440 mg</td>
<td>14</td>
<td>..</td>
<td>*279.28</td>
<td>41.00</td>
<td>Etopophos [LM] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial) Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) Pfizer Australia Pty Ltd [PF] (etoposide 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td><strong>Taxanes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cabazitaxel</strong></td>
<td>Injection 4376H</td>
<td>55 mg</td>
<td>5</td>
<td>..</td>
<td>*2935.78</td>
<td>41.00</td>
<td>Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&amp;) inert substance diluent [4.5 mL vial], 1 pack)</td>
</tr>
<tr>
<td><strong>Docetaxel</strong></td>
<td>Injection 10148D</td>
<td>250 mg</td>
<td>5</td>
<td>..</td>
<td>*182.26</td>
<td>41.00</td>
<td>DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [PF] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

---

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

4662

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must be in combination with prednisone or prednisolone, **AND**
- The treatment must not be used in combination with abiraterone, **AND**
- Patient must have failed treatment with docetaxel due to resistance or intolerance, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.

**Note** Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL are equivalent for the purposes of substitution.

**Note** Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 160 mg in 8 mL and docetaxel solution concentrate for I.V. infusion 160 mg in 16 mL are equivalent for the purposes of substitution.
### NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

**Authority required (STREAMLINED)**

- **6106**
  - Metastatic breast cancer

  **Authority required (STREAMLINED)**

- **6119**
  - HER2 positive breast cancer

---

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>580 mg</td>
<td>5</td>
<td>..</td>
<td>2145.40</td>
<td>41.00</td>
<td>Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

---

**NANOPARTICLE ALBUMIN-BOUND PACLITAXEL**

**Note**
- Special Pricing Arrangements apply.
- Not for use as neoadjuvant or adjuvant therapy.

**Authority required (STREAMLINED)**

- **4657**
  - Stage IV (metastatic) adenocarcinoma of the pancreas

  **Clinical criteria:**
  - The treatment must be in combination with gemcitabine, **AND**
  - The condition must not have been treated previously with PBS-subsidised therapy, **AND**
  - Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less.

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

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>275 mg</td>
<td>11</td>
<td>..</td>
<td>1115.59</td>
<td>41.00</td>
<td>Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

---

**PACLITAXEL**

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>450 mg</td>
<td>3</td>
<td>..</td>
<td>160.26</td>
<td>41.00</td>
<td>Anzatax [PF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Anzatax [PF] (paclitaxel 150 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Anzatax [PF] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Ebewe [SZ] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Kabi [PK] (paclitaxel 30 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxel Kabi [PK] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 150 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 30 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Paclitaxin [TB] (paclitaxel 300 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

---

### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

**Anthracyclines and related substances**

- **DOXORUBICIN**
  - **Injection/intravesical**

  **Authority required (STREAMLINED)**

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>135 mg</td>
<td>11</td>
<td>..</td>
<td>136.93</td>
<td>41.00</td>
<td>Adriamycin [PF] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
</tbody>
</table>

---

**DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)**

**Authority required (STREAMLINED)**

- **4786**
  - Advanced epithelial ovarian cancer

  **Clinical criteria:**
- Patient must have failed a first-line platinum-based chemotherapy regimen.

**Authority required (STREAMLINED)**

### 4791
Metastatic breast cancer

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have failed prior therapy which included capecitabine and a taxane.

**Authority required (STREAMLINED)**

### 4787
Metastatic breast cancer

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have a contraindication to therapy with capecitabine and/or a taxane.

---

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg</td>
<td>5</td>
<td>..</td>
<td>1149.76</td>
<td>41.00</td>
<td>Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
</tbody>
</table>

### **EPIRUBICIN**

**Injection/intravesical**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>220 mg</td>
<td>5</td>
<td>..</td>
<td>166.01</td>
<td>41.00</td>
<td>Epirube [TB] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirube [TB] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin ACT [JU] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin ACT [JU] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epirubicin ACT [JU] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)</td>
</tr>
</tbody>
</table>

### **IDARUBICIN**

**Restricted benefit**
Acute myelogenous leukaemia (AML)

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>5</td>
<td>..</td>
<td>217.90</td>
<td>41.00</td>
<td>Zavedos Solution [PF] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)</td>
</tr>
</tbody>
</table>

### **MITOZANTRONE**

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>5</td>
<td>..</td>
<td>178.38</td>
<td>41.00</td>
<td>Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Onkotrone [BX] (mitozantrone 20 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Onkotrone [BX] (mitozantrone 25 mg/12.5 mL injection, 12.5 mL vial)</td>
</tr>
</tbody>
</table>

### Other cytotoxic antibiotics

### **BLEOMYCIN**

**Restricted benefit**
Germ cell neoplasms

**Restricted benefit**
Lymphoma
### Other Antineoplastic Agents

#### Platinum Compounds

**Carboplatin**

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4309T</td>
<td>DBL Carboplatin [PF] (carboplatin 150 mg/15 mL injection, 15 mL vial)</td>
</tr>
<tr>
<td></td>
<td>DBL Carboplatin [PF] (carboplatin 450 mg/45 mL injection, 45 mL vial)</td>
</tr>
</tbody>
</table>

**Cisplatin**

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4319H</td>
<td>DBL Carboplatin [PF] (cisplatin 100 mg/100 mL injection, 100 mL vial)</td>
</tr>
<tr>
<td></td>
<td>DBL Carboplatin [PF] (cisplatin 50 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

**Oxaliplatin**

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4542C</td>
<td>DBL Oxaliplatin Concentrate [PF] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)</td>
</tr>
<tr>
<td></td>
<td>DBL Oxaliplatin [OC] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

#### Monoclonal Antibodies

**Atezolizumab**

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11277M</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**Atezolizumab**

<table>
<thead>
<tr>
<th>Injection</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11277M</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>
• Patient must have stable or responding disease.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>5</td>
<td>..</td>
<td>*10029.26</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10257**

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing first-line treatment of metastatic disease, as monotherapy, where concomitant bevacizumab has ceased due to intolerance - 4 weekly treatment regimen

**Clinical criteria:**

• Patient must have experienced intolerance to combination treatment with bevacizumab, **AND**

• Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**

• Patient must have stable or responding disease, **AND**

• The treatment must be the sole PBS-subsidised therapy for this condition.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>5</td>
<td>..</td>
<td>*10029.26</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10276**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 3 weekly treatment regimen

**Clinical criteria:**

• Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**

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

• The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**

• The condition must have progressed on or after prior platinum based chemotherapy.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>5</td>
<td>..</td>
<td>*7188.27</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10206**

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

• The condition must be previously untreated, **AND**

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

• The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>3</td>
<td>..</td>
<td>*7188.27</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

### ATEZOLIZUMAB

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.
Authority required (STREAMLINED)

10312
Locally advanced or metastatic non-small cell lung cancer
Treatment Phase: Initial treatment - 4 weekly treatment regimen

Clinical criteria:
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The condition must have progressed on or after prior platinum based chemotherapy.

Injection 11931Y

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>3</td>
<td>..</td>
<td>*10029.26</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**ATEZOLIZUMAB**

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10509
Extensive-stage small cell lung cancer
Treatment Phase: Continuing treatment - 4 weekly treatment regimen

Clinical criteria:
- The treatment must be as monotherapy, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while being treated with this drug for this condition.

Injection 12078Q

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1680 mg</td>
<td>3</td>
<td>..</td>
<td>*10029.26</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**ATEZOLIZUMAB**

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10917
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

Treatment criteria:
- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while being treated with this drug for this condition.

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

Injection 12168K

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1200 mg</td>
<td>8</td>
<td>..</td>
<td>*7188.27</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**ATEZOLIZUMAB**

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10972
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while being treated with this drug for this condition.

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time
### ATEZOLIZUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10216**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease.

**Authority required (STREAMLINED)**

**9345**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfathering treatment

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.

**Clinical criteria:**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must have previously received treatment with these drugs for this condition prior to 1 October 2019, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have a WHO performance status of 0 or 1.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a ‘Grandfathered’ patient must qualify under the ‘Continuing treatment’ criteria.

### ATEZOLIZUMAB

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

**10182**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment 1

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

**Clinical criteria:**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

**Authority required (STREAMLINED)**

**10125**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment 2

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

**Clinical criteria:**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI), **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer.

### ATEZOLIZUMAB

#### Note
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Authorization</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ATEZOLIZUMAB</strong></td>
<td>1200 mg</td>
<td>5</td>
<td>..</td>
<td>*7188.27</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**Authority required (STREAMLINED)**

- **10521**
  - Extensive-stage small cell lung cancer
  - Treatment Phase: Continuing treatment - 3 weekly treatment regimen
  - **Clinical criteria:**
    - The treatment must be as monotherapy, **AND**
    - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
    - Patient must not have developed disease progression while being treated with this drug for this condition.

- **10204**
  - Extensive-stage small cell lung cancer
  - Treatment Phase: Grandfather treatment
  - **Clinical criteria:**
    - Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2020, **AND**
    - The condition must have been untreated prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
    - Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
    - Patient must have had a WHO performance status of 0 or 1 at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
    - The treatment must be in combination with etoposide and a platinum-based antineoplastic if the patient is yet to complete their first 4 cycles of treatment; OR
    - The treatment must be as monotherapy if being administered as maintenance therapy.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

<table>
<thead>
<tr>
<th>Authorization</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ATEZOLIZUMAB</strong></td>
<td>1200 mg</td>
<td>4</td>
<td>..</td>
<td>*7188.27</td>
<td>41.00</td>
<td>Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

**Authority required (STREAMLINED)**

- **10915**
  - Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
  - Treatment Phase: Transitioning from non-PBS-subsidised to PBS-subsidised supply - Grandfather treatment - 3 weekly treatment regimen (1,200 mg) or 4 weekly treatment regimen (1,680 mg where bevacizumab is discontinued)
  - **Clinical criteria:**
    - Patient must have commenced non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 November 2020, **AND**
    - Patient must have met all the PBS eligibility criteria applying to a non-grandfather patient under the Initial treatment restriction for this PBS indication prior to having commenced non-PBS-subsidised treatment with this drug, which are: (i) WHO status score no greater than 1, (ii) Child Pugh class A chronic liver disease, (iii) the patient was unsuitable for transarterial chemoembolization, (iv) the condition was untreated with systemic therapy, unless an intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal had occurred, **AND**
    - Patient must not have developed disease progression while being treated with this drug for this condition.
  - **Treatment criteria:**
    - Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.
A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

### ATEZOLIZUMAB

**Caution** The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** No increase in the maximum amount or number of units may be authorised.

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10939</td>
<td>Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma</td>
</tr>
</tbody>
</table>

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.

**Clinical criteria:**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

### AVELUMAB

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10023</td>
<td>Stage IV (metastatic) Merkel Cell Carcinoma</td>
</tr>
</tbody>
</table>

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction.

### AVELUMAB

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8947</td>
<td>Stage IV (metastatic) Merkel Cell Carcinoma</td>
</tr>
</tbody>
</table>

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.

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

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

4814

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

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm) only if the patient presents with Stage IIIB or Stage IIIC disease, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be commenced in combination with platinum-based chemotherapy, **AND**
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks, **AND**
- The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

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

### BEVACIZUMAB

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

4584

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

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks, **AND**
- The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

### BEVACIZUMAB

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

6337

Advanced carcinoma of cervix

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- Patient must have a Gynaecologic Oncology Group (GOG) performance status of 0 or 1, **AND**
- The condition must not be amenable to curative treatment with surgery; **OR**
- The condition must not be amenable to curative radiation therapy, **AND**
- The condition must be previously untreated with this drug, **AND**
- Patient must not have received prior chemotherapy; **OR**
- Patient must have received prior chemotherapy with radiation therapy, **AND**
- The treatment must be in combination with platinum-based chemotheraphy plus paclitaxel.

Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix.

The patient’s Gynaecologic Oncology Group (GOG) performance status and body weight must be documented in the patient’s medical records at the time the treatment cycle is initiated.
**Authority required (STREAMLINED)**

### 6353

**Advanced carcinoma of cervix**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with platinum-based chemotherapy plus paclitaxel.

Advanced carcinoma of the cervix is defined as persistent carcinoma, recurrent carcinoma or metastatic carcinoma of the cervix.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10881Q</td>
<td>1800 mg</td>
<td>7</td>
<td>..</td>
<td>*5556.66</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

### BEVACIZUMAB

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Relapsed or recurrent glioblastoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have confirmed glioblastoma, **AND**
- Patient must have radiologic evidence of evaluable disease, **AND**
- Patient must have evidence of symptomatic progression, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, temozolomide, **AND**
- Patient must not receive more than 8 weeks of treatment per initial treatment course authorised under this restriction, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- Patient must not have received prior treatment with this drug for this condition, **AND**
- The treatment must not exceed a dose of 10 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 15 mg per kg every 3 weeks.

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

1. a completed authority prescription form;
2. a completed Glioblastoma PBS Authority Application - Supporting Information Form, which includes the following:
   a. evidence of confirmed glioblastoma confirmed by radiology report; and
   b. confirmation that the patient has failed to achieve an adequate response to, or is intolerant to, temozolomide.

Symptomatic progression is defined as:

i) Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; OR

ii) Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11749J</td>
<td>1800 mg</td>
<td>3</td>
<td>..</td>
<td>*5556.66</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

### BEVACIZUMAB

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

### 9346

**Stage IV (metastatic) non-small cell lung cancer (NSCLC)**

**Treatment Phase:** Initial treatment 1

**Treatment criteria:**
- Patient must be undergoing combination treatment with atezolizumab and platinum-doublet chemotherapy.

Clinical criteria:
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
- Patient must not have previously been treated for this condition in the metastatic setting, AND
- Patient must have a WHO performance status of 0 or 1, AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

Authority required (STREAMLINED)

Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment 2

Treatment criteria:
- Patient must be undergoing combination treatment with atezolizumab and platinum-doublet chemotherapy.

Clinical criteria:
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
- Patient must have a WHO performance status of 0 or 1, AND
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, AND
- Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI), AND
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.

Injection 11809M

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1800 mg</td>
<td>5</td>
<td>..</td>
<td>*5556.66</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

**BEVACIZUMAB**

Note Special Pricing Arrangements apply.

**Authority required**
Relapsed or recurrent glioblastoma
Treatment Phase: Grandfathering treatment

Clinical criteria:
- Patient must have confirmed glioblastoma, AND
- Patient must have had radiologic evidence of evaluable disease at the time non-PBS subsidised treatment with this drug for this condition was initiated, AND
- Patient must have had evidence of symptomatic progression at the time non-PBS subsidised treatment with this drug for this condition was initiated, AND
- Patient must have failed to achieve an adequate response to, or be intolerant to, temozolomide, AND
- Patient must have been receiving non-PBS subsidised treatment with this drug for this condition prior to 1 August 2019, AND
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less at the time non-PBS subsidised treatment with this drug for this condition was initiated, AND
- Patient must not have developed further symptomatic progression while being treated with this drug for this condition, AND
- The treatment must not exceed a dose of 10 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 15 mg per kg every 3 weeks.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

The authority application must be made in writing and must include:
1. a completed authority prescription form;
2. a completed Glioblastoma PBS Authority Application - Supporting Information Form, which includes the following:
   a. evidence of confirmed glioblastoma confirmed by radiology report; and
   b. confirmation that the patient has failed to achieve an adequate response to, or is intolerant to, temozolomide.

Symptomatic progression is defined as:
- Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; OR
- Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Authority required
Relapsed or recurrent glioblastoma
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed further symptomatic progression while being treated with this drug for this condition, AND
- The treatment must not exceed a dose of 10 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 15 mg per kg every 3 weeks.
Symptomatic progression is defined as:
  i) Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; OR
  ii) Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema.

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).

Intravenous 11745E
Max. Amount 1800 mg
No. of Rpts 5
Premium $ 5556.66
DPMA $ 41.00
MRVSN $ 41.00
Brand Name and Manufacturer Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

BEVACIZUMAB
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

Authority required (STREAMLINED) 9566
Stage IV (metastatic) non-squamous type non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment
Treatment criteria:
- Patient must be undergoing combination treatment with atezolizumab until disease progression, unless not tolerated.
Clinical criteria:
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Authority required (STREAMLINED) 9454
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfathering treatment
Treatment criteria:
- Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated.
Clinical criteria:
- The condition must be non-squamous type non-small cell lung cancer (NSCLC), AND
- Patient must have previously received treatment with these drugs for this condition prior to 1 October 2019, AND
- Patient must have stable or responding disease, AND
- Patient must have a WHO performance status of 0 or 1.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Intravenous 11803F
Max. Amount 1800 mg
No. of Rpts 7
Premium $ 5556.66
DPMA $ 41.00
MRVSN $ 41.00
Brand Name and Manufacturer Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

BEVACIZUMAB
Caution The safety of atezolizumab in combination with bevacizumab has not been established in patients who have incompletely treated varices, variceal bleeding within the previous 6 months or who are at high risk of bleeding. Patients should be assessed for risk of variceal bleeding prior to treatment with this combination.

Note No increase in the maximum amount or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10959**
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Concurrent use with atezolizumab in hepatocellular carcinoma

**Treatment criteria:**
- Patient must be undergoing combination treatment with PBS-subsidised atezolizumab for this PBS indication.

**Injection 12165G**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1800 mg</td>
<td>8</td>
<td>..</td>
<td>*5556.66</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

**BEVACIZUMAB**

**Authority required (STREAMLINED)**

**4594**
Metastatic colorectal cancer
Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be previously untreated, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with first-line chemotherapy, **AND**
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

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

**Authority required (STREAMLINED)**

**4587**
Metastatic colorectal cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with first-line chemotherapy, **AND**
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

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

**Authority required (STREAMLINED)**

**4939**
Metastatic colorectal cancer
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**
- Patient must have previously treated with PBS-subsidised first-line anti-EGFR antibodies, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with second-line chemotherapy, **AND**
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

**Note** This drug is not PBS-subsidised for use in combination with an anti-EGFR antibody.

**Authority required (STREAMLINED)**

**4968**
Metastatic colorectal cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with second-line chemotherapy, **AND**
- The treatment must not exceed a dose of 5 mg per kg every 2 weeks; OR
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks.

**Note** This drug is not PBS-subsidised for use in combination with an anti-EGFR antibody.

**Note** Bevacizumab is not PBS-subsidised when chemotherapy partners are switched whilst maintaining a bevacizumab backbone in the face of progressive disease.

**Note** The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.
**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, AND
- The condition must not be present in the central nervous system or testis, AND
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, AND
- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, AND
- Patient must not have received more than 1 line of salvage therapy, AND
- Patient must not have received blinatumomab previously for the treatment of minimal residual disease; OR
- Patient must have had a relapse-free period of at least six months following completion of treatment with blinatumomab for minimal residual disease, AND
- The condition must have more than 5% blasts in bone marrow, AND
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.

Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and
4. if applicable, the date of completion of blinatumomab treatment for minimal residual disease and the date of the patient’s subsequent relapse; and
5. the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.

---

**Injection 4400N**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>900 mg</td>
<td>11</td>
<td>..</td>
<td>*2821.22</td>
<td>41.00</td>
<td>Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)</td>
</tr>
</tbody>
</table>

---

**Injection 11118E**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>651 mcg</td>
<td>..</td>
<td>..</td>
<td>*69800.26</td>
<td>41.00</td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] &amp; inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

---

**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

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

**Note** Special Pricing Arrangements apply.
**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

- **Note** Special Pricing Arrangements apply.
- **Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.
- **Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.
- **Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### Authority required
**Acute lymphoblastic leukaemia**

**Clinical criteria:**
- Patient must have a documented history of relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- Patient must have received treatment with this drug for this condition under the Induction treatment restriction for subsequent salvage therapy, **AND**
- Patient must have a documented history of receiving intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must have a documented history of more than 5% blasts in bone marrow, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 October 2019, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- Patient must have achieved a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>784 mcg</td>
<td>..</td>
<td>..</td>
<td>*81419.34 41.00</td>
<td></td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp; inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

### Authority required
**Acute lymphoblastic leukaemia**

**Clinical criteria:**
- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- The condition must not be present in the central nervous system or testis, **AND**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.

### Note
- An increase in maximum number of repeats will be authorised for completion of consolidation therapy.
- A patient may qualify for PBS-subsidised treatment under this restriction once only.
- Patients who have received up to 2 treatment cycles as induction therapy with this drug for this condition prior to 1 October 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.
Patients who have received at least 1 treatment cycle as consolidation therapy with this drug for this condition prior to 1 October 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

Patients who fail to demonstrate a complete remission (CR) or complete remission with incomplete haematological recovery (CRi) after 2 cycles of PBS-subsidised treatment with this agent must cease PBS-subsidised treatment with this agent.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. date of the most recent blinatumomab dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised blinatumomab will be required for completion of induction or consolidation therapy; and
4. date of most recent chemotherapy prior to receiving non-PBS subsidised blinatumomab, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and
5. a copy of the most recent bone marrow biopsy report prior to receiving non-PBS subsidised blinatumomab.

**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

**Authority required**

Acute lymphoblastic leukaemia

**Clinical criteria:**

- Patient must have previously received PBS-subsidised induction treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission; OR
- Patient must have achieved a complete remission with partial haematological recovery, **AND**
- The treatment must not be more than 3 treatment cycles under this restriction in a lifetime, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

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

**Note** Special Pricing Arrangements apply.

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who have received at least 1 treatment cycle as consolidation therapy with this drug for this condition prior to 1 October 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

**Note** Patients who fail to demonstrate a complete remission (CR) or complete remission with incomplete haematological recovery (CRi) after 2 cycles of PBS-subsidised treatment with this agent must cease PBS-subsidised treatment with this agent.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. date of the most recent blinatumomab dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised blinatumomab will be required for completion of induction or consolidation therapy; and
4. date of most recent chemotherapy prior to receiving non-PBS subsidised blinatumomab, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and
5. a copy of the most recent bone marrow biopsy report prior to receiving non-PBS subsidised blinatumomab.

**Authority required**

Acute lymphoblastic leukaemia

**Clinical criteria:**

- Patient must have previously received PBS-subsidised induction treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission; OR
- Patient must have achieved a complete remission with partial haematological recovery, **AND**
- The treatment must not be more than 3 treatment cycles under this restriction in a lifetime, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11814T</td>
<td>651 mcg</td>
<td>..</td>
<td>..</td>
<td>*69800.26</td>
<td>41.00</td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11117D</td>
<td>784 mcg</td>
<td>2</td>
<td>..</td>
<td>*81419.34</td>
<td>41.00</td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

**BLINATUMOMAB**

**Caution** Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

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

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

**Note** Special Pricing Arrangements apply.

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**

**Note** The condition must not be present in the central nervous system or testis, **AND**

**Note** The treatment must not be more than 3 treatment cycles under this restriction in a lifetime, **AND**

**Note** The patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

**Authorisation required**

**Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)**

**Treatment Phase:** Initial treatment of minimal residual disease of Pre-B-cell ALL

**Clinical criteria:**

- Must be treated by a physician experienced in the treatment of haematological malignancies.

**Clinical criteria:**

- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**

- The condition must not be present in the central nervous system or testis, **AND**
- Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy, **AND**
- Patient must have minimal residual disease defined as at least $10^{-4}$ (0.01%) blasts based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL or as subsequent salvage therapy, whichever was the later, and measured using polymerase chain reaction or flow cytometry, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

According to the TGA approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.

For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.

Blinatumomab is not PBS subsidised if it is administered to an in-patient in a public hospital setting.

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

1. a completed authority prescription form; and
2. a completed Minimal residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and
4. the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application

Patients who fail to demonstrate a response to PBS subsidised treatment with this agent at the time where an assessment is required must cease PBS subsidised therapy with this agent.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Treatment Phase: Continuing treatment of previously detectable minimal residual disease of Pre-B-cell ALL

**Treatment criteria:**

- Must be treated by a physician experienced in the treatment of haematological malignancies.

**Clinical criteria:**

- Patient must have previously received PBS subsidised initial treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission, **AND**
- Patient must be minimal residual disease negative, defined as either undetectable using the same method used to determine original eligibility or less than $10^{-4}$ (0.01%) blasts based on measurement in bone marrow, **AND**
- Patient must not develop disease progression while receiving PBS subsidised treatment with this drug for this condition, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.

An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.

Blinatumomab is not PBS subsidised if it is administered to an in-patient in a public hospital setting.

Patients who fail to demonstrate a response to PBS subsidised treatment with this agent at the time where an assessment is required must cease PBS subsidised therapy with this agent.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11850Q</td>
<td>784 mcg</td>
<td>1</td>
<td>..</td>
<td>*81419.34</td>
<td>41.00</td>
<td>Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&amp;) inert substance solution [10 mL vial], 1 pack)</td>
</tr>
</tbody>
</table>

**BRENTUXIMAB VEDOTIN**

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required**

CD30 positive systemic anaplastic large cell lymphoma

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must not have progressive disease, **AND**
• Patient must have previously been issued with an authority prescription for this drug. The treatment must not exceed a lifetime total of 16 cycles.

### BRENTUXIMAB VEDOTIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

### AUTHORITY REQUIRED

- CD30 positive systemic anaplastic large cell lymphoma
- Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be for curative intent, **AND**
- Patient must have undergone appropriate prior front-line curative intent chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease.

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

(a) a completed authority prescription form; and

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

(i) a histology report including evidence of the tumour’s CD30 positivity;

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

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

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

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

### INJECTION 10171H

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>18705.78</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### INJECTION 10166C

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>3</td>
<td>..</td>
<td>18705.78</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### BRENTUXIMAB VEDOTIN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

- Relapsed or Refractory Hodgkin lymphoma
- Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have undergone a primary autologous stem cell transplant (ASCT), **AND**
- Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; OR
- Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT, **AND**
- Patient must not receive more than 4 cycles of treatment under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application.

### BRENTUXIMAB VEDOTIN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Relapsed or Refractory Hodgkin lymphoma
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition, **AND**
- Patient must not be suitable for ASCT for this condition; **OR**
- Patient must not be suitable for treatment with multi-agent chemotherapy for this condition, **AND**
- Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; **OR**
- Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition, **AND**
- Patient must not receive more than 4 cycles of treatment under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application.

### BRENTUXIMAB VEDOTIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Relapsed or Refractory Hodgkin lymphoma
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition, **AND**
- Patient must not be suitable for ASCT for this condition; **OR**
- Patient must not be suitable for treatment with multi-agent chemotherapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 12 cycles of treatment under this restriction.

The treatment must not exceed a total of 16 cycles in a lifetime
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

- **BRENTUXIMAB VEDOTIN**
  
  **Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

  **Note** Special Pricing Arrangements apply.

  **Authority required**
  Relapsed or Refractory Hodgkin lymphoma
  Treatment Phase: Continuing treatment

  **Clinical criteria:**
  - Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition, **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not receive more than 12 cycles of treatment under this restriction.

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

  **Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>18705.78</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

- **BRENTUXIMAB VEDOTIN**

  **Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

  **Note** Special Pricing Arrangements apply.

  **Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au/hpos

  Or mailed to:
  Services Australia
  Complex Drugs
  Reply Paid 9826
  HOBART TAS 7001

  **Authority required**
  CD30 positive cutaneous T-cell lymphoma
  Treatment Phase: Initial treatment

  **Clinical criteria:**
  - Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma, **AND**
  - Patient must have CD30 positivity of at least 3% of malignant cells, **AND**
  - Patient must have a diagnosis of mycosis fungoides; OR
  - Patient must have a diagnosis of Sezary syndrome; OR
  - Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma, **AND**
  - Patient must have received prior systemic treatment for this condition, **AND**
  - The condition must be relapsed or refractory, **AND**
  - The treatment must not exceed 4 cycles under this restriction, **AND**
  - The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

  The authority application must be made in writing and must include:
  (a) a completed authority prescription form; and
  (b) a completed Cutaneous T-cell lymphoma (CTCL) Brentuximab vedotin PBS Authority Application Supporting Information Form which includes the following:
  (i) Evidence of a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and
  (ii) Evidence of CD30 positivity of at least 3% of malignant cells, either from a histology report on the tumour sample or from a flow cytometric analysis of lymphoma cells of the blood; and
  (iii) Date of commencement and completion of the most recent prior systemic treatment.

  **Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>180 mg</td>
<td>3</td>
<td>..</td>
<td>18705.78</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

- **BRENTUXIMAB VEDOTIN**

  **Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

  **Note** Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>11</td>
<td>..</td>
<td>18705.78</td>
<td>41.00</td>
<td>Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
CD30 positive cutaneous T-cell lymphoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have achieved an objective response with this drug, AND
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, AND
- The treatment must not exceed 12 cycles under this restriction.

An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.
The treatment must not exceed a lifetime total of 16 cycles.

CETUXIMAB

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.

Authority required (STREAMLINED)
4788
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx
Treatment Phase: Continuing treatment

Clinical criteria:
- The treatment must be in combination with radiotherapy, AND
- Patient must be unable to tolerate cisplatin; OR
- Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Injection
4435K
Max. Amount No. of Rpts Premium $ DPMA $ MRVSN $ Brand Name and Manufacturer
550 mg 5 .. *1835.12 41.00 Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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

Authority required (STREAMLINED)
4794
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be for the week prior to radiotherapy, AND
- Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Authority required (STREAMLINED)
4785
Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be in combination with radiotherapy, AND
- Patient must be unable to tolerate cisplatin.

Injection
4312Y
Max. Amount No. of Rpts Premium $ DPMA $ MRVSN $ Brand Name and Manufacturer
880 mg .. .. *2709.80 41.00 Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.
Note This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

Authority required (STREAMLINED)
4965
Metastatic colorectal cancer
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have failed to respond to first-line chemotherapy, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

**Authority required (STREAMLINED)**

**4908**
Metastatic colorectal cancer
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be in combination with first-line chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>880 mg</td>
<td>..</td>
<td>..</td>
<td>*2709.80</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Eributx [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
Eributx [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

**CETUXIMAB**

Note Special Pricing Arrangements apply.

Note This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

Note This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.

Note The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.

**Authority required (STREAMLINED)**

**4912**
Metastatic colorectal cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have received an initial authority prescription for this drug for first-line treatment of RAS wild-type metastatic colorectal cancer, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with first-line chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>550 mg</td>
<td>18</td>
<td>..</td>
<td>*1835.12</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Eributx [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
Eributx [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

**CETUXIMAB**

Note Special Pricing Arrangements apply.

Note This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

Note This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.

Note The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient's lifetime.

**Authority required (STREAMLINED)**

**4945**
Metastatic colorectal cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

**INOTUZUMAB OZOGAMICIN**

**Caution** Careful monitoring of patients is required due to risk of developing hepatotoxicity, including life-threatening hepatic veno-occlusive disease, and the increased risk of post-haematopoietic stem cell transplant non-relapse mortality observed in patients treated with inotuzumab.

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

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised induction treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission; **OR**
- Patient must have achieved a complete remission with partial haematological recovery, **AND**
- The treatment must not be more than 5 treatment cycles under this restriction in a lifetime, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

The treatment must not exceed 0.5mg per m² for all doses within a treatment cycle

Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.

**INOTUZUMAB OZOGAMICIN**

**Caution** Careful monitoring of patients is required due to risk of developing hepatotoxicity, including life-threatening hepatic veno-occlusive disease, and the increased risk of post-haematopoietic stem cell transplant non-relapse mortality observed in patients treated with inotuzumab.

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patients are eligible to receive a loading dose for the first dose of a treatment cycle while receiving induction treatment. Two prescriptions are required, the first prescription for the loading dose at a dose no higher than 0.8mg per m², and the second prescription for two doses at a dose no higher than 0.5mg per m². Both prescriptions must be submitted with the initial application.

**Note** Once a patient achieves complete remission or complete remission with partial haematological recovery, a new prescription must be written under the consolidation treatment phase.

**Note** A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.

**Note** A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.

**Note** Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

**Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos**

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826

HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

Clinical criteria:
- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
• Patient must not have received more than 1 line of salvage therapy, **AND**
• Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
• The condition must be CD22-positive, **AND**
• The condition must have more than 5% blasts in bone marrow, **AND**
• The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.

This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

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

1. two completed authority prescription forms;
2. a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and
3. evidence that the condition is CD22-positive; and
4. a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

The treatment must not exceed 6 treatment cycles in a lifetime.

**IPILIMUMAB**

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

**8555**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**

• The condition must not have previously been treated, **AND**
• The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
• Patient must have a WHO performance status of 2 or less, **AND**
• The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.

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

**Note** For patients who commence therapy with ipilimumab:

1. Decisions concerning efficacy should await completion of the entire induction regimen (four doses) and should be made in conjunction with established criteria for immunological responses. However induction may be ceased or delayed if symptomatic progressive disease or intolerable adverse events occur and if, in the opinion of the clinician, continuation of treatment poses a risk to the patient;
2. Tumour responses may occur beyond the initial 12 week induction phase and evaluation for potential later responses should be undertaken regularly for the first year.
Authority required (STREAMLINED)

6585
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Re-induction treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction), AND
- The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.
  (i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or
  (ii) a partial or complete response.
  The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated.

Caution
Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

Authority required (STREAMLINED)

10122
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Induction treatment

Clinical criteria:
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, AND
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, AND
- The condition must not be ocular or uveal melanoma, AND
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.
  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.
  Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.
  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

### NIVOLUMAB

Note
No increase in the maximum number of repeats may be authorised.
Note
Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10117
Locally advanced or metastatic non-small cell lung cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, AND
- Patient must have stable or responding disease.
  Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### NIVOLUMAB

Note
No increase in the maximum number of repeats may be authorised.
Note
Special Pricing Arrangements apply.
• Patient must not have developed disease progression while being treated with this drug for this condition, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

### NIVOLUMAB

**Note** Special Pricing Arrangements apply.

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

#### Authority required (STREAMLINED)

**9252**

Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have stable or responding disease, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

### NIVOLUMAB

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

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**9214**

Unresectable Stage III or Stage IV malignant melanoma

**Treatment Phase:** Maintenance treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have stable or responding disease.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

#### Authority required (STREAMLINED)

**9298**

Unresectable Stage III or Stage IV malignant melanoma

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have stable or responding disease.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.
• Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition, AND
• The treatment must be as monotherapy for this condition, AND
• Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

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

### NIVOLUMAB

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

10155

Unresectable Stage III or Stage IV malignant melanoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**

• Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
• Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### Injection

10745M

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>11</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

10165

Locally advanced or metastatic non-small cell lung cancer

**Treatment Phase:** Initial treatment

**Clinical criteria:**

• Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, AND
• Patient must have a WHO performance status of 0 or 1, AND
• The treatment must have progressed on or after prior platinum based chemotherapy.

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

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

### Injection

10764M

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>8</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

### Injection

11158G

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>8</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>
**Authority required (STREAMLINED)**

**9216**

Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition.

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

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

**Injection 11435W**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>8</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

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

**Note** Special Pricing Arrangements apply.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

**Authority required (STREAMLINED)**

**9312**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial Treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; **OR**
- Patient must have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.

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

Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

**Injection 11150W**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>480 mg</td>
<td>8</td>
<td>..</td>
<td>*10054.18</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**NIVOLUMAB**

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10195**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, **AND**
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
• The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.
  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

Authority required (STREAMLINED)

111
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Grandfathered patients treated with nivolumab as first-line therapy in unresectable Stage III or Stage IV malignant melanoma prior to 1 March 2020

Clinical criteria:
• Patient must have received non-PBS-subsidised supply of this drug as first-line therapy for unresectable Stage III or Stage IV malignant melanoma prior to 1 March 2020, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
  A patient may qualify for PBS-subsidised treatment under this restriction once only.
  For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.
  Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

Injection 11543M

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mg</td>
<td>3</td>
<td>..</td>
<td>2577.88</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

NIVOLUMAB

Caution Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

Note Special Pricing Arrangements apply.

Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Authority required (STREAMLINED)

8573
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Induction treatment

Clinical criteria:
• The condition must not have previously been treated, AND
• The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), AND
• Patient must have a WHO performance status of 2 or less, AND
• The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.
  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.
  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

Injection 11636K

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>360 mg</td>
<td>3</td>
<td>..</td>
<td>7562.08</td>
<td>41.00</td>
<td>Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.
Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection, AND
- Patient must not have experienced disease recurrence, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.

Authority required
Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma
Treatment Phase: Grandfather treatment

Clinical criteria:
- Patient must have previously received non-PBS-subsidised drug for adjuvant treatment following complete surgical resection prior to 1 March 2020, AND
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, AND
- Patient must not have evidence of recurrence, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must not have received prior PBS-subsidised treatment for this condition, AND
- Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, AND
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.
A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.
For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

[Injection Table]

[OBINUTUZUMAB]
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage II bulky or Stage III/IV follicular lymphoma
Treatment Phase: Maintenance therapy

Clinical criteria:
- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated initial restriction; OR
- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated grandfather restriction, AND
- The condition must be CD20 positive, AND
- Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition, AND
- The treatment must be maintenance therapy, AND
- The treatment must be the sole PBS subsidised treatment for this condition, AND
- The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, AND
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

[Injection Table]

[OBINUTUZUMAB]
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Follicular lymphoma
Treatment Phase: Maintenance therapy

Clinical criteria:
• Patient must have previously received PBS subsidised treatment with this drug under the rituximab refractory initial restriction; OR
• Patient must have previously received PBS subsidised treatment with this drug under the rituximab refractory grandfather restriction, AND
• The condition must be CD20 positive, AND
• The condition must have been refractory to treatment with rituximab, AND
• Patient must have demonstrated a partial or complete response to PBS subsidised re-induction treatment with this drug for this condition, AND
• The treatment must be maintenance therapy, AND
• The treatment must be the sole PBS subsidised treatment for this condition, AND
• The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, AND
• Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

<table>
<thead>
<tr>
<th>Injection 11468N</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>5</td>
<td>..</td>
<td>*5378.78</td>
<td>41.00</td>
<td></td>
<td>Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)</td>
</tr>
</tbody>
</table>

### OBINUTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**

Follicular lymphoma

**Treatment Phase: Re-induction treatment**

**Clinical criteria:**

• Patient must not have previously received PBS subsidised obinutuzumab, AND
• The condition must be CD20 positive, AND
• The condition must be refractory to treatment with rituximab for this condition, AND
• The condition must be symptomatic, AND
• The treatment must be for re-induction treatment purposes only, AND
• The treatment must be in combination with bendamustine, AND
• The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition.

The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or
ii) the rituximab-refractory re-induction restriction; or
iii) the previously untreated grandfather restriction; or
iv) the rituximab-refractory grandfather restriction.

**Authority required**

Follicular lymphoma

**Treatment Phase: Grandfather treatment - rituximab refractory**

**Clinical criteria:**

• Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, AND
• The condition must be CD20 positive, AND
• The condition must have been refractory to treatment with rituximab prior to initiating non-PBS treatment this drug for this condition, AND
• Patient must not have developed disease progression while receiving treatment with this drug for this condition, AND
• The treatment must be in combination with bendamustine for re-induction treatment, AND
• The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition; OR
• Patient must have demonstrated a partial or complete response to re-induction treatment with this drug for this condition, AND
• The treatment must be the sole PBS subsidised treatment for maintenance treatment; AND
• The treatment must not exceed 12 doses or 2 years duration of maintenance treatment, whichever comes first, AND
• The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or
ii) the rituximab-refractory re-induction restriction; or
iii) the previously untreated grandfather restriction; or
iv) the rituximab-refractory grandfather restriction.
### OBINUTUZUMAB

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

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

**Note** Special Pricing Arrangements apply.

### Authority required

**Stage II bulky or Stage III/IV follicular lymphoma**

**Treatment Phase: Induction treatment**

**Clinical criteria:**
- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:
- i) the previously untreated induction treatment restriction; or
- ii) the rituximab-refractory re-induction restriction; or
- iii) the previously untreated grandfather restriction; or
- iv) the rituximab-refractory grandfather restriction.

### Authority required

**Stage II bulky or Stage III/IV follicular lymphoma**

**Treatment Phase: Grandfather treatment - previously untreated setting**

**Clinical criteria:**
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, **AND**
- The condition must be CD20 positive, **AND**
- The condition must have been untreated prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be in combination with chemotherapy for induction treatment, **AND**
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition; **OR**
- Patient must have demonstrated a partial or complete response to induction treatment with this drug for this condition for maintenance treatment, **AND**
- The treatment must be the sole PBS subsidised treatment for maintenance treatment; **AND**
- The treatment must not exceed 12 doses or 2 years duration of maintenance treatment, whichever comes first.

A patient may only qualify for PBS subsidised initiated treatment once in a lifetime under:
- i) the previously untreated induction treatment restriction; or
- ii) the rituximab-refractory re-induction restriction; or
- iii) the previously untreated grandfather restriction; or
- iv) the rituximab-refractory grandfather restriction.

### Injection 11457B

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>7</td>
<td>..</td>
<td>*5378.78</td>
<td>41.00</td>
<td>Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)</td>
</tr>
</tbody>
</table>

### Injection 11458C

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>9</td>
<td>..</td>
<td>*5378.78</td>
<td>41.00</td>
<td>Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)</td>
</tr>
</tbody>
</table>

### OBINUTUZUMAB

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

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

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

11015

**Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)**

**Treatment Phase: For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy**

**Clinical criteria:**
- The condition must be untreated, **AND**
- The treatment must be in combination with PBS-subsidised venetoclax.

### Injection 12204H

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>8</td>
<td>..</td>
<td>*5378.78</td>
<td>41.00</td>
<td>Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)</td>
</tr>
</tbody>
</table>
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

**OBINUTUZUMAB**

- **Note** Obinutuzumab is not to be used as monotherapy or in combination with anti-cancer drugs other than chlorambucil under this restriction. For use with venetoclax, refer to the separate listing for this purpose.
- **Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

- **11052**
  - Chronic lymphocytic leukaemia (CLL)
  - Treatment Phase: Combination use with chlorambucil only
  - **Clinical criteria:**
    - The condition must be CD20 positive, **AND**
    - The condition must be previously untreated, **AND**
    - Patient must be inappropriate for fludarabine based chemo-immunotherapy, **AND**
    - The treatment must be in combination with chlorambucil, **AND**
    - Patient must have a creatinine clearance 30 mL/min or greater, **AND**
    - Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); **OR**
    - Patient must have a creatinine clearance less than 70 mL/min.

  Treatment must be discontinued in patients who experience disease progression whilst on this treatment.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>7</td>
<td>..</td>
<td>*5378.78</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Brand Name and Manufacturer**

- Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

**PANITUMUMAB**

- **Note** This drug is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

**Authority required (STREAMLINED)**

- **5439**
  - Metastatic colorectal cancer
  - Treatment Phase: Initial treatment
  - **Clinical criteria:**
    - Patient must have RAS wild-type metastatic colorectal cancer, **AND**
    - Patient must have a WHO performance status of 2 or less, **AND**
    - The condition must have failed to respond to first-line chemotherapy, **AND**
    - The treatment must be as monotherapy; **OR**
    - The treatment must be in combination with chemotherapy, **AND**
    - The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

**Authority required (STREAMLINED)**

- **5447**
  - Metastatic colorectal cancer
  - Treatment Phase: Continuing treatment
  - **Clinical criteria:**
    - Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy, **AND**
    - Patient must not have progressive disease, **AND**
    - The treatment must be as monotherapy; **OR**
    - The treatment must be in combination with chemotherapy, **AND**
    - The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

- **Note** This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.

- **Note** The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient’s lifetime.

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>720 mg</td>
<td>5</td>
<td>..</td>
<td>*3878.76</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Brand Name and Manufacturer**

- Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)
- Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)
### PANITUMUMAB

**Note** Special Pricing Arrangements apply.
**Note** Panitumumab is not PBS-subsidised for use in combination with another anti-EGFR antibody or in combination with an anti-VEGF antibody.

**Authority required (STREAMLINED)**

**5526**
Metastatic colorectal cancer
Treatment Phase: Initial Treatment

**Clinical criteria:**
- Patient must have RAS wild-type metastatic colorectal cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be in combination with first-line chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

**Authority required (STREAMLINED)**

**5452**
Metastatic colorectal cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have received an initial authority prescription for panitumumab for first-line treatment of RAS wild-type metastatic colorectal cancer, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with first-line chemotherapy, **AND**
- The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.

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

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

**Note** This drug is not PBS-subsidised when chemotherapy partners are switched whilst maintaining an anti-EGFR antibody backbone in the face of progressive disease.

**Note** The treatment must not exceed a single course of therapy with this drug for metastatic colorectal cancer in a patient’s lifetime.

#### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>720 mg</td>
<td>9</td>
<td>..</td>
<td>*3878.76</td>
<td>41.00</td>
<td>Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)</td>
</tr>
</tbody>
</table>

### PEMBROLIZUMAB

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required (STREAMLINED)**

**10705**
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment - 3 weekly treatment regimen

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have stable or responding disease.

#### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>7</td>
<td>..</td>
<td>*8135.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

### PEMBROLIZUMAB

**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required (STREAMLINED)**

**10701**
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously been issued with an authority prescription for this drug for this condition, AND
- Patient must have stable or responding disease.

### Injection

**12124D**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg</td>
<td>3</td>
<td>..</td>
<td>*16185.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

#### Authority required (STREAMLINED)

**10696**

Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must not exceed a total of 6 doses under this restriction.

### Injection

**10493G**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>5</td>
<td>..</td>
<td>*8135.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

#### Authority required (STREAMLINED)

**10689**

Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, AND
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The treatment must not exceed a total of 3 doses under this restriction.

### Injection

**12128H**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg</td>
<td>2</td>
<td>..</td>
<td>*16185.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

Note No increase in the maximum number of repeats may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
**Authority required (STREAMLINED)**

**9921**

Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy; **OR**
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; **OR**
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

**9894**

Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

**Injection 11646Y**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>8135.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

### PEMBROLIZUMAB

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**

Relapsed or Refractory Hodgkin lymphoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; **OR**
- Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition, **AND**
- Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form;
(b) a completed Hodgkin lymphoma pembrolizumab PBS Authority Application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Relapsed or Refractory Hodgkin lymphoma

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, AND

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### PEMBROLIZUMAB

**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.
- Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**
- Resected Stage IIB, Stage IIC or Stage IIID malignant melanoma
  - Treatment Phase: Initial treatment - 6 weekly treatment regimen
  - Clinical criteria:
    - Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection, AND
    - Patient must have a WHO performance status of 1 or less, AND
    - The treatment must be the sole PBS-subsidised therapy for this condition, AND
    - Patient must not have received prior PBS-subsidised treatment for this condition, AND
    - The treatment must commence within 12 weeks of complete resection, AND
    - Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Note**
- Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**
- Resected Stage IIB, Stage IIC or Stage IIID malignant melanoma
  - Treatment Phase: Continuing treatment - 6 weekly treatment regimen
  - Clinical criteria:
    - Patient must have previously received non-PBS-subsidised treatment for this condition, AND
    - The treatment must commence within 12 weeks of complete surgical resection, AND
    - Patient must not have experienced disease recurrence, AND
    - The treatment must be the sole PBS-subsidised therapy for this condition, AND
    - Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**
- Resected Stage IIB, Stage IIC or Stage IIID malignant melanoma
  - Treatment Phase: Grandfather treatment - 6 weekly treatment regimen
  - Clinical criteria:
    - Patient must have previously received non-PBS-subsidised drug for adjuvant treatment following complete surgical resection prior to 1 September 2020, AND
    - Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, AND
    - Patient must not have evidence of recurrence, AND
    - The treatment must be the sole PBS-subsidised therapy for this condition, AND
    - Patient must not have received prior PBS-subsidised treatment for this condition, AND
    - Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, AND
    - Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

A patient may qualify for PBS-subsidised treatment with this drug, a Grandfathered patient must qualify under the Continuing treatment criteria.

### PEMBROLIZUMAB

**Note**
- Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**
Resected Stage III B, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:
- The treatment must be adjuvant to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required**
Resected Stage III B, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**
Resected Stage III B, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Grandfather treatment - 3 weekly treatment regimen

Clinical criteria:
- Patient must have previously received non-PBS-subsidised drug for adjuvant treatment following complete surgical resection prior to 1 September 2020, **AND**
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, **AND**
- Patient must not have evidence of recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

---

**PEMBROLIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required (STREAMLINED)**

**10681**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:
- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement in material, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Authority required (STREAMLINED)**

**10682**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Chemotherapy items for Public Hospital use

**PEMBROLIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** A patient may only qualify for PBS subsidised treatment under this restriction once.

**Note** Following completion of the initial PBS subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

### Injection 11494Y

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>*8135.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**Authority required [STREAMLINED]**

### 10697

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Grandfather treatment - 3 weekly treatment regimen

**Clinical criteria:**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note** A patient may only qualify for PBS subsidised treatment under this restriction once.

**Note** Following completion of the initial PBS subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

### 10704

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Initial treatment - 6 weekly treatment regimen

**Clinical criteria:**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019, **AND**
- Patient must not have had been treated for this condition in the metastatic setting prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1 prior to initiation of non-PBS subsidised treatment with this drug for this condition, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed a total of 4 doses under this restriction.

**Note** In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

### 10693

Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Continuing treatment - 6 weekly treatment regimen

**Clinical criteria:**
- Patient must have previously received PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under this restriction.

**Authority required [STREAMLINED]**

### 10683

**Antineoplastic and Immunomodulating Agents**
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfather treatment - 6 weekly treatment regimen

**Clinical criteria:**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must not have had treatment with this drug for this condition prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under this restriction.

**Note**
In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

**Note**
A patient may only qualify for PBS-subsidised treatment under this restriction once.

**Note**
Following completion of the initial PBS subsidised course, further applications for treatment will be assessed under the continuing treatment restriction.

### Injection

<table>
<thead>
<tr>
<th>12119W</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg</td>
<td>3</td>
<td>..</td>
<td>*16185.78</td>
<td>41.00</td>
<td></td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PEMBROLIZUMAB**

**Note**
No increase in the maximum amount or number of units may be authorised.

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

**Note**
Special Pricing Arrangements apply.

**Note**
Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

**Authority required**
Relapsed or refractory primary mediastinal B-cell lymphoma
Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient's medical records, **AND**
- Patient must have been treated with rituximab-based chemotherapy for this condition, **AND**
- Patient must be experiencing relapsed/refractory disease, **AND**
- Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; OR
- Patient must have undergone an autologous stem cell transplant (ASCT); OR
- Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form;
(b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application, which includes:
(i) confirmation that histology results with PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient's medical records;
(ii) details of prior treatments for this condition.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
**Authority required**
Relapsed or refractory primary mediastinal B-cell lymphoma
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 35 cycles in a lifetime.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Relapsed or refractory primary mediastinal B-cell lymphoma
Treatment Phase: Grandfather treatment (initial treatment of a patient commenced on non-PBS-subsidised treatment)

**Clinical criteria:**
- Patient must have received treatment with this drug for this condition prior to 1 September 2020, **AND**
- The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient's medical records, **AND**
- Patient must have been treated with rituximab-based chemotherapy prior to initiating treatment with this drug for this condition, **AND**
- Patient must have been experiencing relapsed/refractory disease prior to initiating treatment with this drug for this condition, **AND**
- Patient must have been autologous stem cell transplant (ASCT) ineligible following a single line of treatment prior to initiating treatment with this drug for this condition; OR
- Patient must have undergone an autologous stem cell transplant (ASCT) prior to initiating treatment with this drug for this condition; OR
- Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must have included rituximab-based chemotherapy, prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have received treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 35 cycles in a lifetime, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

Applications for authorisation of initial treatment must be in writing and must include:
- (a) a completed authority prescription form;
- (b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application for Grandfathered patients, which includes:
  - (i) confirmation that history results and PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient's medical records;
  - (ii) details of prior treatments for this condition

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Injection

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg</td>
<td>6</td>
<td>..</td>
<td>*8135.78</td>
<td>41.00</td>
<td>Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)</td>
</tr>
</tbody>
</table>

**PERTUZUMAB**

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au
Public

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must not have received prior anti-HER2 therapy for this condition, **AND**
- Patient must not have received prior chemotherapy for this condition, **AND**
- The treatment must be in combination with trastuzumab and a taxane, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH).
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10267J</td>
<td>840 mg</td>
<td>..</td>
<td>..</td>
<td>*6230.52</td>
<td>41.00</td>
<td>Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**PERTUZUMAB**

*Note* No increase in the maximum quantity or number of units may be authorised.
*Note* No increase in the maximum number of repeats may be authorised.
*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).
*Note* The criterion that limits breaks in treatment with pertuzumab under this restriction has been temporarily modified due to the current risk of COVID-19. This allows an extended break in therapy with PBS-subsidised pertuzumab in patients who are at risk of COVID-19.

**Authority required**
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be in combination with trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
The treatment must not exceed a lifetime total of one course. However, treatment breaks are permitted. A patient who has a treatment break in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug.
Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMA</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10333W</td>
<td>420 mg</td>
<td>3</td>
<td>..</td>
<td>*3158.15</td>
<td>41.00</td>
<td>Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)</td>
</tr>
</tbody>
</table>

**RITUXIMAB**

**Authority required (STREAMLINED)**
7400
Previously untreated or relapsed/refractory CD20 positive lymphoid cancer
Treatment Phase: Induction or re-induction therapy

**Clinical criteria:**
• The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
• The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
• The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, AND
• The treatment must be in combination with chemotherapy, AND
• Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia.

### Injection 4614W

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>7</td>
<td>..</td>
<td>*1641.27</td>
<td>41.00</td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

#### RITUXIMAB

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

**Authority required (STREAMLINED)**

10227

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

**Treatment Phase: Re-induction therapy**

**Clinical criteria:**

• The treatment must be for re-induction treatment purposes only, AND
• The condition must have relapsed or be refractory to treatment, AND
• Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

### Injection 11936F

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>3</td>
<td>..</td>
<td>*1641.27</td>
<td>41.00</td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>

#### RITUXIMAB

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

**Authority required (STREAMLINED)**

9542

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

**Treatment Phase: Maintenance therapy**

**Clinical criteria:**

• The treatment must be maintenance therapy, AND
• Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current treatment with this drug for this condition, AND
• Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

### Injection 4613T

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>7</td>
<td>..</td>
<td>*1641.27</td>
<td>41.00</td>
<td>Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)</td>
</tr>
</tbody>
</table>
RITUXIMAB

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

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, AND
- The treatment must be in combination with chemotherapy, AND
- Patient must be in complete remission, AND
- Patient must not receive more than 6 doses in total under this restriction.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4615X</td>
<td>800 mg</td>
<td>5</td>
<td>..</td>
<td>*1641.27</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer

- Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
- Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)
- Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
- Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)
- Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
- Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

RITUXIMAB

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

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

Authority required (STREAMLINED)

9451

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

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current treatment with this drug for this condition, AND
- Patient must not have received bendamustine induction therapy, AND
- The treatment must be maintenance therapy, AND
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>10179R</td>
<td>800 mg</td>
<td>11</td>
<td>..</td>
<td>*1641.27</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer

- Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
- Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)
- Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
- Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial)
- Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
- Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

TRASTUZUMAB

Note: Increased maximum amounts can be requested where a patient's weight is greater than 125 kg.

Note: Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED)

10296

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
• Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**Injection 4632T**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 mg</td>
<td>..</td>
<td>..</td>
<td>*1684.63</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB**

**Note** Increased maximum quantity will be authorised where a patient requires a new loading dose due to a break in therapy of more than 1 week but less than 6 weeks from the last dose or a patient’s weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINEd)**

10213
Early HER2 positive breast cancer
Treatment Phase: Continuing treatment (weekly regimen)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

**Injection 4639E**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>250 mg</td>
<td>9</td>
<td>..</td>
<td>*932.23</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB**

**Note** Increased maximum quantity will be authorised where a patient requires a new loading dose due to a break in therapy of more than 1 week but less than 6 weeks from the last dose or a patient’s weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINEd)**

10294
Early HER2 positive breast cancer
Treatment Phase: Continuing treatment (3 weekly regimen)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

**Injection 4703M**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 mg</td>
<td>3</td>
<td>..</td>
<td>*2437.02</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>
### TRASTUZUMAB

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

**Note** Increased maximum quantity may be authorised where a patient's weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED) 9353**

Metastatic (Stage IV) HER2 positive breast cancer

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- Patient must have evidence of a human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>10391X</td>
<td>1000 mg</td>
<td>..</td>
<td>..</td>
<td>*3283.46</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer:
- Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)
- Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)
- Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)
- Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)
- Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)
- Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)
- Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)
- Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)
- Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

---

### TRASTUZUMAB

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

**Note** Increased maximum quantity may be authorised where a patient's weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED) 9349**

Metastatic (Stage IV) HER2 positive breast cancer

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, a new loading dose may be required.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>10401K</td>
<td>750 mg</td>
<td>3</td>
<td>..</td>
<td>*2437.02</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer:
- Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)
- Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)
- Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)
- Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)
- Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)
- Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)
- Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)
- Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)
- Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

---

### TRASTUZUMAB

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

**Note** Increased maximum quantity may be authorised where a patient's weight is greater than 125 kg.

**Note** Authority applications for increased quantities/ repeats (where relevant) 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).
Antineoplastic and Immunomodulating Agents

Authority required (STREAMLINED) 9573
Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity as demonstrated by immunohistochemistry 2+ or more in tumour material, AND
- Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on more than 6 copies of HER2 in the same tumour tissue sample, AND
- Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on the ratio of HER2 to chromosome 17 being more than 2 in the same tumour tissue sample, AND
- Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; OR
- Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil, AND
- Patient must not have previously received this drug for this condition, AND
- Patient must not have received prior chemotherapy for this condition, AND
- Patient must have a WHO performance status of 2 or less,
- 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.
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

Injection 10581X

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg</td>
<td>..</td>
<td>..</td>
<td>*3283.46</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OOQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

TRASTUZUMAB
Note: No increase in the maximum number of repeats may be authorised.
Note: Increased maximum quantity will be authorised where a patient requires a new loading dose due to a break in therapy of more than 1 week but less than 6 weeks from the last dose or a patient’s weight is greater than 125 kg.
Note: Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED) 9571
Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Injection 10588G

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 mg</td>
<td>3</td>
<td>..</td>
<td>*2437.02</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzant [OOQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

TRASTUZUMAB
Note: No increase in the maximum number of repeats may be authorised.
Note: Increased maximum amounts can be requested where a patient’s weight is greater than 125 kg.
Note: Authority applications for increased quantities/ repeats (where relevant) 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 (STREAMLINED) 10293
Early HER2 positive breast cancer
Schedule of Pharmaceutical Benefits – December 2020

Treatment Phase: Initial treatment (3 weekly regimen)

**Clinical criteria:**
- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; **OR**
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

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

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4650R</td>
<td>1000 mg</td>
<td>..</td>
<td>..</td>
<td>*3283.46</td>
<td>41.00</td>
<td>Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ontruzani [OQ] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB EMTANSINE**

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

**Note** Increased maximum amounts can be requested where a patient’s weight is greater than 125 kg.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; **OR**
- The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:
  - (i) details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;
  - (ii) dates of treatment with trastuzumab and pertuzumab; and
  - (iii) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or
  - (iv) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
- Services Australia
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer, **AND**
Chemotherapy items for Public Hospital use

**Antineoplastic and immunomodulating agents**

- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

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

**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).

### Injection

<table>
<thead>
<tr>
<th>10282E</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>450 mg</td>
<td>8</td>
<td>..</td>
<td><strong>7643.66</strong></td>
<td>41.00</td>
<td></td>
<td>Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB EMTANSINE**

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

**Note** Increased maximum amounts can be requested where a patient's weight is greater than 125 kg.

### Authority required

**Early HER2 positive breast cancer**

**Treatment Phase: Initial adjuvant treatment**

**Clinical criteria:**

- The treatment must be prescribed within 12 weeks after surgery, **AND**
- Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report, **AND**
- Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.

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 details from the pathology report from an approved pathology authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Early HER2 positive breast cancer**

**Treatment Phase: Continuing adjuvant treatment**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.

**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).

### Authority required

**Early HER2 positive breast cancer**

**Treatment Phase: Grandfather adjuvant treatment**

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug as adjuvant treatment of early HER2 positive breast cancer prior to 1 April 2020, **AND**
The treatment must have been prescribed within 12 weeks after surgery prior to commencing treatment with this drug, AND

Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report, AND

Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery, AND

Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND

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

The treatment must not extend beyond 42 weeks (14 cycles) duration using non-PBS-subsidised and PBS-subsidised drug supply obtained under the grandfather restriction and the continuing treatment restrictions combined.

Authority applications for grandfather 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 details from the pathology report from an approved pathology authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery and the number of non-PBS-subsidised cycles of treatment received by the patient.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia 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 Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Injection**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>450 mg</td>
<td>6</td>
<td>..</td>
<td>7643.66</td>
<td>41.00</td>
<td>Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**Other antineoplastic agents**

**ARSENIC**

**Authority required (STREAMLINED)**

**6018**

Acute promyelocytic leukaemia

Treatment Phase: Induction and consolidation treatment

**Clinical criteria:**

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

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 mg</td>
<td>140</td>
<td>..</td>
<td>572.78</td>
<td>41.00</td>
<td>Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)</td>
</tr>
</tbody>
</table>

**ARSENIC**

**Authority required (STREAMLINED)**

**4793**

Acute promyelocytic leukaemia

Treatment Phase: Induction and consolidation treatment

**Clinical criteria:**

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

- The condition must be relapsed, AND

- Patient must be arsenic naive at induction.

**Authority required (STREAMLINED)**

**5997**

Acute promyelocytic leukaemia

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

### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

7962

Multiple myeloma

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

**Clinical criteria:**

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have previously received 8 treatment cycles of bortezomib for progressive disease, **AND**
- Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib, **AND**
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, **AND**
- Patient must not have a gap of more than 10 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition following completion of 8 treatment cycles, **AND**
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient’s medical records. 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 prescribing. A response assessment prior to cycle 9 must be documented in the patient’s medical records. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.

## Injection 4371C

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 mg</td>
<td>89</td>
<td>..</td>
<td>*572.78</td>
<td>41.00</td>
<td>Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)</td>
</tr>
</tbody>
</table>

## Injection 4712B

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>11</td>
<td>..</td>
<td>*1341.87</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

## BORTEZOMIB

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

7960

Multiple myeloma

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

**Clinical criteria:**

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have previously received 8 treatment cycles of bortezomib in the current treatment course, **AND**
- Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib, **AND**
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, **AND**
- Patient must not have a gap of more than 10 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition following completion of 8 treatment cycles, **AND**
- Patient must not receive more than 3 cycles of bortezomib under this restriction.
Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient’s medical records.

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.

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

---

### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

#### 7940

**Symptomatic multiple myeloma**

**Treatment Phase: Continuing PBS-subsidised treatment**

**Clinical criteria:**

- Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and be ineligible for high dose chemotherapy, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved a best confirmed response to bortezomib at the time of prescribing, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide, **AND**
- Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction. Continuing PBS-subsidised supply requires that the gap between the initial PBS-subsidised treatment with this drug for this condition and the continuing treatment is no more than 6 months.

#### 7941

**Symptomatic multiple myeloma**

**Treatment Phase: Continuing PBS-subsidised treatment**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for newly diagnosed symptomatic multiple myeloma, **AND**
- Patient must have severe acute renal failure, **AND**
- Patient must have demonstrated at least a partial response at the completion of cycle 4, **AND**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction. A copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority and diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient’s medical records.

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:
### BORTEZOMIB

**Note** The criterion that limits up to 4 cycles of treatment with bortezomib under this restriction has been temporarily removed due to the current risk of COVID-19. This allows continuity of treatment with PBS-subsidised bortezomib in those patients whose transplant may be delayed at this time.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**10338**

Symptomatic multiple myeloma

**Clinical criteria:**
- Patient must be newly diagnosed, **AND**
- Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with chemotherapy.

Details of the histological diagnosis of multiple myeloma must be documented in the patient’s medical records.

#### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**7961**

Multiple myeloma

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

**Clinical criteria:**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with chemotherapy.

Progressive disease is defined as at least 1 of the following:
- at least a 25% reduction and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- 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
- in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- 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
- an increase in the size or number of lytic bone lesions (not including compression fractures); or
- 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
- 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. 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 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 must be documented in the patient’s medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient’s medical records:
- the level of serum monoclonal protein; or
- the level of serum monoclonal protein. The difference between involved and uninvolved serum monoclonal protein free light chain concentration.

### Injection 4429D

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>19</td>
<td>..</td>
<td>*1341.87</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 1 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### Injection 4732C

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>15</td>
<td>..</td>
<td>*1341.87</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 1 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>
(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 must 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) must be documented in the patient’s medical records. 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 documented in the patient's medical records.

**Authority required (STREAMLINED)**

7974
Multiple myeloma
Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment

**Clinical criteria:**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, AND
- Patient must have previously received 4 treatment cycles of bortezomib for progressive disease, **AND**
- Patient must have demonstrated at least a partial response to bortezomib, **AND**
- Patient must not have received more than 2 treatment cycles after first achieving a confirmed complete response, **AND**
- Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient’s medical records.

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 mcg 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 level of serum M protein (monoclonal protein).

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 prescribing.

A response assessment prior to cycle 5 must be documented in the patient’s medical records.

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.

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4706Q</td>
<td>3000 mcg</td>
<td>15</td>
<td>..</td>
<td>*1341.87</td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**BORTEZOMIB**

**Note**
Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

7938
Multiple myeloma
Treatment Phase: Retreatment of Progressive disease - Initial PBS-subsidised treatment

**Clinical criteria:**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have progressive disease, **AND**
- Patient must have previously been treated with PBS-subsidised bortezomib, **AND**
- Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy, **AND**
Chemotherapy items for Public Hospital use

- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved 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 lesion 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.

Details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters that will be used to assess response, and diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously documented must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient’s medical records:

(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 must be used to determine response, results for either (a) or (b) or (c) must be documented in the patient’s medical records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records.

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 documented in the patient’s medical records.

**Authority required (STREAMLINED)**

**7939**

Multiple myeloma

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

**Clinical criteria:**

- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have previously received 4 treatment cycles of bortezomib in the current treatment course, **AND**
- Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib, **AND**
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, **AND**
- Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient’s medical records.

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 prescribing.
A response assessment prior to cycle 5 must be documented in the patient’s medical records.
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.

### BORTEZOMIB

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**10455**
Symptomatic multiple myeloma

**Clinical criteria:**
- The condition must be newly diagnosed, **AND**
- Patient must be ineligible for high dose chemotherapy, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

**Authority required (STREAMLINED)**

**10426**
Symptomatic multiple myeloma

**Clinical criteria:**
- The condition must be newly diagnosed, **AND**
- Patient must have severe acute renal failure, **AND**
- Patient must require dialysis; **OR**
- Patient must be at high risk of requiring dialysis in the opinion of a nephrologist, **AND**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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 must be documented in the patient’s medical records. 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 documented in the patient’s medical records 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 documented in the patient’s medical records.

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 documented in the patient’s medical records.

---

<table>
<thead>
<tr>
<th>Injection</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4713C</td>
<td>3000 mcg</td>
<td>15</td>
<td>..</td>
<td>*1341.87</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Velcade [JC] (bortezomib 3 mg injection, 1 vial)
Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)
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.

**Authority required (STREAMLINED)**

**10454**

Multiple myeloma

Treatment Phase: Triple combination therapy (bortezomib, lenalidomide and dexamethasone)

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The treatment must be in combination with lenalidomide and dexamethasone, **AND**
- The treatment must not be in combination with PBS-subsidised thalidomide, pomalidomide or carfilzomib, **AND**
- The treatment must not be changing from dual combination therapy with lenalidomide and dexamethasone for symptomatic multiple myeloma to triple therapy with lenalidomide, bortezomib and dexamethasone, **AND**
- Patient must not receive more than 8 cycles of treatment with bortezomib under this restriction.

**Injection 4403R**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000 mcg</td>
<td>31</td>
<td>..</td>
<td><em>1341.87</em></td>
<td>41.00</td>
<td>Velcade [JC] (bortezomib 1 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Velcade [JC] (bortezomib 3 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

**CARFILZOMIB**

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

**Note** No increase in the maximum amount or number of units may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- Patient must not receive more than three cycles of treatment 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 in 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.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised 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 in 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.

### Injection 11229B

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mg</td>
<td>17</td>
<td>..</td>
<td>$2623.66</td>
<td>41.00</td>
<td>Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial)</td>
</tr>
</tbody>
</table>

### ERIBULIN

Note: A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.

**Authority required (STREAMLINED)**

4649

Locally advanced or metastatic breast cancer

**Clinical criteria:**
- Patient must have progressive disease, **AND**
- Patient must have failed at least two prior chemotherapeutic regimens for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

### Injection 10144X

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mg</td>
<td>13</td>
<td>..</td>
<td>$769.78</td>
<td>41.00</td>
<td>Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)</td>
</tr>
</tbody>
</table>

### ERIBULIN

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

**Authority required (STREAMLINED)**

7258

Advanced (unresectable and/or metastatic) liposarcoma

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Patient must have an ECOG performance status of 2 or less, **AND**
- The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must be aged 18 years or older.

### Injection 11212D

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mg</td>
<td>7</td>
<td>..</td>
<td>$769.78</td>
<td>41.00</td>
<td>Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)</td>
</tr>
</tbody>
</table>

### IRINOTECAN

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

**Authority required (STREAMLINED)**

7280

Advanced (unresectable and/or metastatic) liposarcoma

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease while being treated with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must be aged 18 years or older.

### Injection 4451G

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>800 mg</td>
<td>11</td>
<td>..</td>
<td>$150.66</td>
<td>41.00</td>
<td>Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)</td>
</tr>
</tbody>
</table>
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

Chemotherapy items for Public Hospital use

- Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
- MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
- MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)
- Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
- Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)

---

### Topotecan Injection 4617B

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3500 mcg</td>
<td>17</td>
<td>..</td>
<td>*117.86</td>
<td>41.00</td>
<td>Hycamtin [SZ] (topotecan 4 mg injection, 5 vials)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Topotecan Accord [OC] (topotecan 4 mg/4 mL injection, 5 x 4 mL vials)</td>
</tr>
</tbody>
</table>
## Related Pharmaceutical Benefits for Public Hospital use

<table>
<thead>
<tr>
<th>Category</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALIMENTARY TRACT AND METABOLISM</td>
<td>144</td>
</tr>
<tr>
<td></td>
<td>ANTIEMETICS AND ANTINAUSEANTS</td>
</tr>
<tr>
<td></td>
<td>ANTIEMETICS AND ANTINAUSEANTS</td>
</tr>
<tr>
<td>ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS</td>
<td>148</td>
</tr>
<tr>
<td></td>
<td>ANTINEOPLASTIC AGENTS</td>
</tr>
<tr>
<td></td>
<td>OTHER ANTINEOPLASTIC AGENTS</td>
</tr>
<tr>
<td></td>
<td>IMMUNOSTIMULANTS</td>
</tr>
<tr>
<td></td>
<td>IMMUNOSTIMULANTS</td>
</tr>
<tr>
<td>VARIOUS</td>
<td>151</td>
</tr>
<tr>
<td></td>
<td>ALL OTHER THERAPEUTIC PRODUCTS</td>
</tr>
<tr>
<td></td>
<td>ALL OTHER THERAPEUTIC PRODUCTS</td>
</tr>
</tbody>
</table>
ANTIEMETICS AND ANTINAUSEANTS

Serotonin (5HT3) antagonists

GRANISETRON

Restricted benefit
Nausea and vomiting

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

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

<table>
<thead>
<tr>
<th>granisetron 3 mg/3 mL injection, 3 mL ampoule</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>1.92</td>
<td>3.21</td>
<td>*</td>
<td>* Granisetron-AFT [AE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Granisetron Kabi [PK]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>granisetron 2 mg tablet, 1</th>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*16.58</td>
<td>17.87</td>
<td></td>
<td>Kytril [IX]</td>
</tr>
</tbody>
</table>

NETUPITANT + PALONOSETRON

Note No increase in the maximum number of repeats may be authorised.
Note No increase in the maximum quantity or number of units may be authorised.
Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Authority required (STREAMLINED)

5991
Nausea and vomiting

Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, AND
- The treatment must be in combination with dexamethasone, AND
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

5994
Nausea and vomiting

Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND
- The treatment must be in combination with dexamethasone, AND
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6937
Nausea and vomiting

Clinical criteria:
- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, \( \text{AND} \)
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, \( \text{AND} \)
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, \( \text{AND} \)
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6879
Nausea and vomiting

Clinical criteria:
- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

### Netupitant 300 mg + Palonosetron 500 microgram capsule, 1

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10714X</td>
<td>5</td>
<td>..</td>
<td>97.16</td>
<td>41.00</td>
<td>Akynzeo [MF]</td>
</tr>
</tbody>
</table>

## ONDANSETRON

- **Restricted benefit**
- Nausea and vomiting

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

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

### Ondansetron 4 mg/5 mL oral liquid, 50 mL

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5848T</td>
<td>..</td>
<td>..</td>
<td>80.78</td>
<td>41.00</td>
<td>Zofran syrup 50 mL [AS]</td>
</tr>
</tbody>
</table>

### Ondansetron 4 mg tablet, 4

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5967C</td>
<td>..</td>
<td>..</td>
<td>3.41</td>
<td>4.70</td>
<td>Ondansetron AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron APOTEX [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron Mylan Tablets [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zoferan [AS]</td>
</tr>
</tbody>
</table>

### Ondansetron 8 mg tablet, 4

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5968D</td>
<td>..</td>
<td>..</td>
<td>5.35</td>
<td>6.64</td>
<td>Ondansetron AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron APOTEX [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron Mylan Tablets [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zoferan [AS]</td>
</tr>
</tbody>
</table>

## ONDANSETRON

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

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

### Ondansetron 4 mg orally disintegrating tablet, 4

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5857G</td>
<td>..</td>
<td>..</td>
<td>3.41</td>
<td>4.70</td>
<td>Ondansetron ODT [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron Mylan ODT [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron ODT GH [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zotren ODT [RF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron AN ODT [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron ODT-DRLA [RZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron SZ ODT [HX]</td>
</tr>
</tbody>
</table>

### Ondansetron 8 mg orally disintegrating tablet, 4

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5858H</td>
<td>..</td>
<td>..</td>
<td>5.35</td>
<td>6.64</td>
<td>Ondansetron ODT [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron Mylan ODT [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron ODT GH [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zotren ODT [RF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron AN ODT [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron ODT-DRLA [RZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ondansetron SZ ODT [HX]</td>
</tr>
</tbody>
</table>

### Ondansetron 4 mg wafer, 4

<table>
<thead>
<tr>
<th>Dose</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5969E</td>
<td>..</td>
<td>..</td>
<td>2.28</td>
<td>5.69</td>
<td>Zofran Zydis [AS]</td>
</tr>
</tbody>
</table>
### PALONOSETRON

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

**Note** This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

**Related**

- **ondansetron 8 mg wafer, 4**
- **palonosetron 250 microgram/5 mL injection, 5 mL vial**
- **tropisetron 5 mg/5 mL injection, 5 mL ampoule**

**Other antiemetics**

- **APREPIANT**

**Authority required (STREAMLINED)**

- **4223**
- **4216**
- **6464**
No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

**Authority required (STREAMLINED)**

**6383**

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

---

**FOSAPREPIANT**

**Note:** This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

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

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

---

### Aprepitant 165 mg capsule, 1

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2550F</td>
<td>1</td>
<td>62.30</td>
<td>41.00</td>
<td></td>
<td>Aprepitant APOTEX [TX]</td>
</tr>
</tbody>
</table>

---

**Authority required (STREAMLINED)**

**6886**

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6891**

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**6887**

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dacarbazine; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**Authority required (STREAMLINED)**

**6852**

Nausea and vomiting

**Clinical criteria:**
- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.
fosaprepitant 150 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emend IV [MK]</td>
<td>97.16</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Monoclonal antibodies**

### RITUXIMAB

**Authority required (STREAMLINED)**

7400

- Previously untreated or relapsed/refractory CD20 positive lymphoid cancer
- Treatment Phase: Induction or re-induction therapy

**Clinical criteria:**
- The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
- The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
- The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia for induction course (including consolidation course).

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mabthera SC [RO]</td>
<td>1699.12</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Note**

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

---

### RITUXIMAB

**Authority required (STREAMLINED)**

7399

- Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia
- Treatment Phase: Maintenance therapy

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mabthera SC [RO]</td>
<td>1699.12</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Note**

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

---

### RITUXIMAB

**Authority required (STREAMLINED)**

6011

- Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma
- Treatment Phase: Maintenance therapy

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMA $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mabthera SC [RO]</td>
<td>1699.12</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Note**

No increase in the maximum number of repeats may be authorised.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Related Pharmaceutical Benefits for Public Hospital use

149

Related Authority required (STREAMLINED)

10227
Relapsed or refractory follicular B-cell non-Hodgkin’s lymphoma
Treatment Phase: Re-induction therapy

Clinical criteria:
• The treatment must be for re-induction treatment purposes, AND
• The condition must have relapsed or be refractory to treatment, AND
• Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11942M</td>
<td>1</td>
<td>2</td>
<td>1699.12</td>
<td>41.00</td>
<td>Mabthera SC [RO]</td>
</tr>
</tbody>
</table>

• RITUXIMAB

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

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

Authority required (STREAMLINED)

6161
Stage III or IV CD20 positive follicular B-cell non-Hodgkin’s lymphoma
Treatment Phase: Maintenance therapy

Clinical criteria:
• Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, AND
• Patient must not have received bendamustine induction therapy, AND
• The treatment must be maintenance therapy, AND
• Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10710Q</td>
<td>1</td>
<td>11</td>
<td>1699.12</td>
<td>41.00</td>
<td>Mabthera SC [RO]</td>
</tr>
</tbody>
</table>

• TRASTUZUMAB

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).

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

Authority required (STREAMLINED)

10212
Early HER2 positive breast cancer
Treatment Phase: 3 weekly treatment regimen

Clinical criteria:
• Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), AND
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND
• Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
• Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

trastuzumab 600 mg/5 mL injection, 5 mL vial

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10743K</td>
<td>1</td>
<td>3</td>
<td>1470.22</td>
<td>41.00</td>
<td>Herceptin SC [RO]</td>
</tr>
</tbody>
</table>

• TRASTUZUMAB

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

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

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).

Authority required (STREAMLINED)

9353
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, AND
- The treatment must not be in combination with nab-paclitaxel, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10811B</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>1470.22</td>
<td>41.00 Herceptin SC [RO]</td>
</tr>
</tbody>
</table>

**TRASTUZUMAB**

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

**IMMUNOSTIMULANTS**

**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)**

9462
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10817H</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>1470.22</td>
<td>41.00 Herceptin SC [RO]</td>
</tr>
</tbody>
</table>

**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)**

6678
Myeloproliferative disease
Clinical criteria:
- Patient must have excessive thrombocytosis.

**interferon alfa-2a 9 million units (33.333 microgram)/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5998Q</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*363.00</td>
<td>41.00 Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**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)**

6661
Low grade non-Hodgkin's lymphoma
Clinical criteria:
- The condition must have clinical features suggestive of a poor prognosis, AND
- The treatment must be in combination with anthracycline-based chemotherapy.

**interferon alfa-2a 3 million units (11.111 microgram)/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5946Y</td>
<td>15</td>
<td>5</td>
<td>..</td>
<td>*363.15</td>
<td>41.00 Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**interferon alfa-2a 9 million units (33.333 microgram)/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5949D</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*363.00</td>
<td>41.00 Roferon-A [RO]</td>
</tr>
</tbody>
</table>
- **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)**
    - 6662
      - Hairy cell leukaemia
  - **Authority required (STREAMLINED)**
    - 6678
      - Myeloproliferative disease
  - **Clinical criteria:**
    - Patient must have excessive thrombocytosis.

  interferon alfa-2a 3 million units (11.111 microgram)/0.5 mL injection, 0.5 mL syringe
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>4</td>
<td>..</td>
<td>363.15</td>
<td>41.00</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

- **MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN**
  - **Restricted benefit**
  - Primary and relapsing superficial urothelial carcinoma of the bladder

  Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, 3 vials
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>399.49</td>
<td>41.00</td>
<td>OncoTICE [MK]</td>
</tr>
</tbody>
</table>

- **VARIOUS**

- **ALL OTHER THERAPEUTIC PRODUCTS**
  - **Detoxifying agents for antineoplastic treatment**

- **FOLINIC ACID**

  folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>43.80</td>
<td>41.00</td>
<td>Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]</td>
</tr>
</tbody>
</table>

  folinic acid 300 mg/30 mL injection, 30 mL vial
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>1</td>
<td>..</td>
<td>42.12</td>
<td>41.00</td>
<td>Leucovorin Calcium (Hospira Pty Limited) [PF]</td>
</tr>
</tbody>
</table>

- **FOLINIC ACID**
  - **Note**: For item codes 5890B and 1899Y, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

  folinic acid 50 mg/5 mL injection, 5 mL vial
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>2</td>
<td>..</td>
<td>38.90</td>
<td>40.19</td>
<td>*Leucovorin Calcium (Hospira Pty Limited) [PF]</td>
</tr>
</tbody>
</table>

  folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>38.90</td>
<td>40.19</td>
<td>*Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]</td>
</tr>
</tbody>
</table>

- **FOLINIC ACID**
  - **Restrict benefit**
  - Megaloblastic anaemias
  - **Clinical criteria:**
    - The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

  folinic acid 15 mg tablet, 10
  
<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>76.00</td>
<td>41.00</td>
<td>Leucovorin Calcium (Hospira Pty Limited) [PF]</td>
</tr>
</tbody>
</table>

- **MESNA**
  - **Restricted benefit**
  - Urothelial toxicity
Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**
- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

### mesna 1 g/10 mL injection, 15 x 10 mL ampoules

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5961R</td>
<td>1</td>
<td>..</td>
<td>150.63</td>
<td>41.00</td>
<td>Uromitexan [BX]</td>
</tr>
</tbody>
</table>

### mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

<table>
<thead>
<tr>
<th>Max. Amount</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMA $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5960Q</td>
<td>1</td>
<td>..</td>
<td>66.52</td>
<td>41.00</td>
<td>Uromitexan [BX]</td>
</tr>
</tbody>
</table>
Index of Manufacturers' Code
<table>
<thead>
<tr>
<th>Code</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>AFT Pharmaceuticals (AU) Pty Ltd</td>
</tr>
<tr>
<td>AF</td>
<td>Alphapharm Pty Ltd</td>
</tr>
<tr>
<td>AN</td>
<td>Amgen Australia Pty Limited</td>
</tr>
<tr>
<td>AP</td>
<td>AstraZeneca Pty Ltd</td>
</tr>
<tr>
<td>AS</td>
<td>Aspen Pharmacare Australia Pty Limited</td>
</tr>
<tr>
<td>BQ</td>
<td>Bristol-Myers Squibb Australia Pty Ltd</td>
</tr>
<tr>
<td>BX</td>
<td>Baxter Healthcare Pty Limited</td>
</tr>
<tr>
<td>EA</td>
<td>Amneal Pharmaceuticals Pty Ltd</td>
</tr>
<tr>
<td>EI</td>
<td>Eisai Australia Pty Ltd</td>
</tr>
<tr>
<td>EW</td>
<td>Celltrion Healthcare Australia Pty Ltd</td>
</tr>
<tr>
<td>FB</td>
<td>Pierre Fabre Australia Pty Ltd</td>
</tr>
<tr>
<td>FF</td>
<td>Phebra Pty Ltd</td>
</tr>
<tr>
<td>GQ</td>
<td>Generic Health Pty Ltd</td>
</tr>
<tr>
<td>GX</td>
<td>Apotex Pty Ltd</td>
</tr>
<tr>
<td>HX</td>
<td>Sandoz Pty Ltd</td>
</tr>
<tr>
<td>IX</td>
<td>Clinet Pty Ltd</td>
</tr>
<tr>
<td>JC</td>
<td>Janssen-Cilag Pty Ltd</td>
</tr>
<tr>
<td>JO</td>
<td>Juno Pharmaceuticals Pty Ltd</td>
</tr>
<tr>
<td>JU</td>
<td>Juno Pharmaceuticals Pty Ltd</td>
</tr>
<tr>
<td>LM</td>
<td>Link Medical Products Pty Ltd</td>
</tr>
<tr>
<td>LR</td>
<td>Cipla Australia Pty Ltd</td>
</tr>
<tr>
<td>LY</td>
<td>Eli Lilly Australia Pty Ltd</td>
</tr>
<tr>
<td>MF</td>
<td>Mundipharma Pty Limited</td>
</tr>
<tr>
<td>MK</td>
<td>Merck Sharp &amp; Dohme (Australia) Pty Ltd</td>
</tr>
<tr>
<td>OC</td>
<td>Accord Healthcare Pty Ltd</td>
</tr>
<tr>
<td>OD</td>
<td>Accord Healthcare Pty Ltd</td>
</tr>
<tr>
<td>OE</td>
<td>Omegapharm Pty Ltd</td>
</tr>
<tr>
<td>OQ</td>
<td>Organon Pharma Pty Ltd</td>
</tr>
<tr>
<td>PF</td>
<td>Pfizer Australia Pty Ltd</td>
</tr>
<tr>
<td>PK</td>
<td>Fresenius Kabi Australia Pty Limited</td>
</tr>
<tr>
<td>RA</td>
<td>Sun Pharma ANZ Pty Ltd</td>
</tr>
<tr>
<td>RF</td>
<td>Arrow Pharma Pty Ltd</td>
</tr>
<tr>
<td>RO</td>
<td>Roche Products Pty Ltd</td>
</tr>
<tr>
<td>RZ</td>
<td>Dr Reddy's Laboratories (Australia) Pty Ltd</td>
</tr>
<tr>
<td>SE</td>
<td>Servier Laboratories (Aust.) Pty Ltd</td>
</tr>
<tr>
<td>SG</td>
<td>Merck Healthcare Pty Ltd</td>
</tr>
<tr>
<td>SW</td>
<td>sanofi-aventis Australia Pty Ltd</td>
</tr>
<tr>
<td>SZ</td>
<td>Sandoz Pty Ltd</td>
</tr>
<tr>
<td>TB</td>
<td>Teva Pharma Australia Pty Limited</td>
</tr>
<tr>
<td>TK</td>
<td>Takeda Pharmaceuticals Australia Pty Ltd</td>
</tr>
<tr>
<td>TS</td>
<td>Specialised Therapeutics Australia Pty Ltd</td>
</tr>
<tr>
<td>TX</td>
<td>Apotex Pty Ltd</td>
</tr>
</tbody>
</table>
Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate)
Irinotecan Alphapharm [AF] (irinotecan hydrochloride)
IRINOTECAN
IPILIMUMAB
Imfinzi [AP] (durvalumab 500 mg/injection, 5 vials)
IFOSFAMIDE
Hycamtin [SZ] (topotecan 4 mg injection, 5 mL vials)
Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)
Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 mL vial)
Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)
Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 100 mL vial)
Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)
Folinic Acid
Folinys [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)
FOSAPREPITANT
FOTEMUSTINE
Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)
GEMCITABINE
GRANISETRON
Granisetron Kabi (PK)
Granisetron-AFT (AE)
Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)
Herceptin SC [RO]
Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) 60, 61, 62, 63, 127, 128, 129, 130
Herceptin [RO] (trastuzumab 60 mg injection, 1 vial) 60, 61, 62, 63, 127, 128, 129, 130
Herceptin [EW] (trastuzumab 150 mg injection, 1 vial) 60, 61, 62, 63, 127, 128, 129, 130
Holoxan [BX] (ifosfamide 1 g injection, 1 vial)
Holoxan [BX] (ifosfamide 2 g injection, 1 vial)
Hyacint [SZ] (topotecan 4 mg injection, 5 mL vials)
IDARUBICIN
IFOSFAMIDE
Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)
INOTIZUMAB OZOGAMICIN
INTERFERON ALFA-2A
IPILIMUMAB
IRINOTECAN
Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)
Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] & inert substance diluent [4.5 mL vial] 1 pack)
Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)
Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)
Kanjinti [AN] (trastuzumab 150 mg injection, 1 vial) 60, 61, 62, 63, 127, 128, 129, 130
Kanjinti [AN] (trastuzumab 420 mg injection, 1 vial) 60, 61, 62, 63, 127, 129, 130
Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) 49, 50, 51, 52, 53, 54, 55, 56, 116, 117, 118, 119, 120, 121, 122, 123
Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) 73, 140
Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) 73, 140
Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial) 73, 140
Kytril [IX]
Leucovorin Calcium ( Hospira Pty Limited) [PF]
Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]
Leustatin [JC] ( cladribine 10 mg/10 mL injection, 10 mL vial)
Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)
Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)
Litar [AF] ( cladribine 10 mg/5 mL injection, 5 mL vial)
Mabthera SC [RO]
Mabthera [RO] ( rituximab 100 mg/10 mL injection, 2 x 10 mL vials)
Mabthera [RO] ( rituximab 500 mg/50 mL injection, 50 mL vial)
MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)
MESNA
Methotecad [RO] (methotrexate 1 g/10 mL injection, 10 mL vial)
METHOTREXATE
Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)
Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial)
Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)
MITOZANTRONE
Mitoxantrone Ebewe [SZ] (mitoxantrone 20 mg/10 mL injection, 10 mL vial)
Muphoran [SE] ( fotemustine 208 mg injection [1 vial] & inert substance diluent [4 mL ampoule] 1 pack)
MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN [BCG]) TICE STRAIN
NANOPARTICLE ALBUMIN-BOUND PACLITAXEL
Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial)
Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial)
NETUPITANT + PALONOSETRON
NIVOLUMAB
OBINUTUZUMAB
Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)
Omgemaphal Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)
OncoTICE [MK]
ONDANSETRON
Ondasenron AN [EA]
Ondasenron AN ODT [EA]
Ondasenron APOTEX [GX]
Ondasenron Mylan ODT [AF]
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Page Numbers</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zofran Zydis (AS)</td>
<td>145, 146</td>
<td>159</td>
</tr>
<tr>
<td>Zofran (AS)</td>
<td>145</td>
<td>159</td>
</tr>
<tr>
<td>Zotren ODT (RF)</td>
<td>145</td>
<td>159</td>
</tr>
</tbody>
</table>