



**Australian Government**

**Department of Health**



# Schedule of Pharmaceutical Benefits

Efficient Funding of Chemotherapy

**Effective 1 September 2019**



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# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2019. 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)

### Deletions

#### **Deletion – Item**

- 10240Y **OFATUMUMAB**,  
ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials (*Arzerra*)
- 10237T **OFATUMUMAB**,  
ofatumumab 1 g/50 mL injection, 50 mL vial (*Arzerra*)
- 10239X **OFATUMUMAB**,  
ofatumumab 1 g/50 mL injection, 50 mL vial (*Arzerra*)

#### **Deletion – Brand**

- 10424P *Keytruda*, MK – **PEMBROLIZUMAB**, pembrolizumab 50 mg injection, 1 vial
- 10475H *Keytruda*, MK – **PEMBROLIZUMAB**, pembrolizumab 50 mg injection, 1 vial
- 11352L *Keytruda*, MK – **PEMBROLIZUMAB**, pembrolizumab 50 mg injection, 1 vial

### Alterations

#### **Alteration – Item Description**

##### *From*

- 10424P **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial pembrolizumab 50 mg injection, 1 vial (*Keytruda*)

##### *To*

- 10424P **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial (*Keytruda*)

##### *From*

- 10475H **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial pembrolizumab 50 mg injection, 1 vial (*Keytruda*)

##### *To*

- 10475H **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial (*Keytruda*)

##### *From*

- 11352L **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial pembrolizumab 50 mg injection, 1 vial (*Keytruda*)

##### *To*

- 11352L **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial (*Keytruda*)

#### **Alteration – Note**

- 10775D **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 11143L **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)

---

**Alteration – Restriction**

|        |                                                                                                                                                     |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| 10748Q | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 10775D | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11143L | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11152Y | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11157F | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11159H | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11425H | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11434T | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11626X | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |

**Alteration – Maximum Quantity**

|        |                                                                                                                                                     | <i>From</i> | <i>To</i> |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------|
| 10748Q | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 10775D | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11143L | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11152Y | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11157F | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11159H | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11425H | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11434T | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11626X | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |

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## Efficient Funding of Chemotherapy (Public Hospital)

### Deletions

#### Deletion – Item

- 10249K **OFATUMUMAB**,  
ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials (*Arzerra*)
- 10236R **OFATUMUMAB**,  
ofatumumab 1 g/50 mL injection, 50 mL vial (*Arzerra*)
- 10252N **OFATUMUMAB**,  
ofatumumab 1 g/50 mL injection, 50 mL vial (*Arzerra*)

#### Deletion – Brand

- 10436G *Keytruda*, MK – **PEMBROLIZUMAB**, pembrolizumab 50 mg injection, 1 vial
- 10493G *Keytruda*, MK – **PEMBROLIZUMAB**, pembrolizumab 50 mg injection, 1 vial
- 11330H *Keytruda*, MK – **PEMBROLIZUMAB**, pembrolizumab 50 mg injection, 1 vial

### Alterations

#### Alteration – Item Description

##### From

- 10436G **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial pembrolizumab 50 mg injection, 1 vial (*Keytruda*)

##### To

- 10436G **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial (*Keytruda*)

##### From

- 10493G **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial pembrolizumab 50 mg injection, 1 vial (*Keytruda*)

##### To

- 10493G **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial (*Keytruda*)

##### From

- 11330H **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial pembrolizumab 50 mg injection, 1 vial (*Keytruda*)

##### To

- 11330H **PEMBROLIZUMAB**, pembrolizumab 100 mg/4 mL injection, 4 mL vial (*Keytruda*)

#### Alteration – Note

- 10764M **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 11158G **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 11411N **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)

#### Alteration – Restriction

- 10745M **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 10764M **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 11150W **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 11153B **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)
- 11158G **NIVOLUMAB**,  
nivolumab 40 mg/4 mL injection, 4 mL vial (*Opdivo*);  
nivolumab 100 mg/10 mL injection, 10 mL vial (*Opdivo*)

|        |                                                                                                                                                     |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| 11160J | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11411N | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11435W | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |
| 11642R | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) |

#### **Alteration – Maximum Quantity**

|        |                                                                                                                                                     | <i>From</i> | <i>To</i> |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-----------|
| 10745M | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 10764M | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11150W | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11153B | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11158G | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11160J | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11411N | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11435W | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |
| 11642R | <b>NIVOLUMAB,</b><br>nivolumab 40 mg/4 mL injection, 4 mL vial ( <i>Opdivo</i> );<br>nivolumab 100 mg/10 mL injection, 10 mL vial ( <i>Opdivo</i> ) | 360         | 480       |

## **Related Pharmaceutical Benefits for Public Hospital use**

### **Advance Notices**

**1 October 2019**

#### **Deletion – Brand**

|       |                                                                                   |
|-------|-----------------------------------------------------------------------------------|
| 5967C | <i>Onsetron 4, ZP – ONDANSETRON</i> , ondansetron 4 mg tablet, 4                  |
| 5968D | <i>Onsetron 8, ZP – ONDANSETRON</i> , ondansetron 8 mg tablet, 4                  |
| 5971G | <i>Onsetron, ZP – ONDANSETRON</i> , ondansetron 4 mg/2 mL injection, 2 mL ampoule |
| 5972H | <i>Onsetron, ZP – ONDANSETRON</i> , ondansetron 8 mg/4 mL injection, 4 mL ampoule |

# 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](http://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](http://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 |
| <sup>a</sup> or <sup>b</sup> | 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 (\$7.39)
- Preparation fee (\$85.06)
- Distribution fee (\$27.02)
- Diluent fee (\$5.35)

### Section 94 Approved Public Hospital Authority

- Preparation fee (\$85.06)

### Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee (\$7.39)
- Preparation fee (\$85.06)
- Distribution fee (\$27.02) (not payable where the drug is trastuzumab)
- Diluent fee (\$5.35)

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# Pharmaceutical Benefits Schedules

# Chemotherapy items for Private Hospital use

|                                                    |    |
|----------------------------------------------------|----|
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## ■ 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                   |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|        | 200 mg      | 11          | ..         | *1762.06 | 40.30    | Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial)<br>Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial) |

### ■ CYCLOPHOSPHAMIDE

#### **Injection**

| 7226H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 2800 mg     | 17          | ..         | *197.51 | 40.30    | Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial)<br>Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial)<br>Endoxan [BX] (cyclophosphamide 500 mg injection, 1 vial) |

### ■ IFOSFAMIDE

#### **Injection**

| 7248L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                        |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------|
|       | 4000 mg     | 19          | ..         | *324.22 | 40.30    | Holoxan [BX] (ifosfamide 1 g injection, 1 vial)<br>Holoxan [BX] (ifosfamide 2 g injection, 1 vial) |

#### *Nitrosoureas*

## ■ FOTEMUSTINE

### Authority required (STREAMLINED)

6288

Metastatic malignant melanoma

### Injection

| 7245H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                              |
|-------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------------------------------------------------|
|       | 220 mg      | 8           | ..         | *2004.98 | 40.30    | Muphoran [SE] (fotemustine 208 mg injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack) |

## ANTIMETABOLITES

### *Folic acid analogues*

## ■ METHOTREXATE

### Injection

| 7250N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 250 mg      | 5           | ..         | *150.67 | 40.30    | Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial)<br>Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1)<br>Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)<br>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

### Injection

| 7251P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 20000 mg    | ..          | ..         | *888.78 | 40.30    | Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial)<br>Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1)<br>Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)<br>Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) |

## ■ PEMETREXED

### Injection

| 7255W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                             |
|-------|-------------|-------------|------------|---------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 1100 mg     | 5           | ..         | *210.30 | 40.30    | Alimta [LY] (pemetrexed 100 mg injection, 1 vial)<br>Alimta [LY] (pemetrexed 500 mg injection, 1 vial)<br>DBL Pemetrexed [PF] (pemetrexed 1 g injection, 1 vial)<br>DBL Pemetrexed [PF] (pemetrexed 100 mg injection, 1 vial)<br>DBL Pemetrexed [PF] (pemetrexed 500 mg injection, 1 vial)<br>Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial)<br>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-DRLA [RZ] (pemetrexed 100 mg injection, 1 vial)  
 Pemetrexed DRLA [RZ] (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)

## ■ 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**

| 11271F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                               |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------|
|        | 80 mg       | 5           | ..         | *4545.86 | 40.30    | Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL 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: 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**

| 11278N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                               |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------|
|        | 80 mg       | 11          | ..         | *4545.86 | 40.30    | Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial) |

## ■ 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**

| 7256X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                       |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------|
|       | 7 mg        | 8           | ..         | *1182.26 | 40.30    | Tomudex [PF] (raltitrexed 2 mg injection, 1 vial) |

### *Purine analogues*

## ■ CLADRIBINE

### Authority required (STREAMLINED)

**6265**

Hairy cell leukaemia

### **Injection**

| 7225G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                              |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------|
|       | 17 mg       | 6           | ..         | *1179.82 | 40.30    | Leustatin [JC] (cladribine 10 mg/10 mL injection, 10 mL vial)<br>Litak [OA] (cladribine 10 mg/5 mL injection, 5 mL vial) |

## ■ 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

| 7233Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 55 mg       | 29          | ..         | *189.40 | 40.30    | Fludarabine ACT [JU] (fludarabine phosphate 50 mg injection, 1 vial)<br>Fludarabine AMNEAL [JU] (fludarabine phosphate 50 mg injection, 1 vial)<br>Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials) |

## *Pyrimidine analogues*

### ■ CYTARABINE

# Injection

| 7227J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                      |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------|
|       | 7000 mg     | 15          | ..         | *934.02 | 40.30    | Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials) |

### ■ FLUOROURACIL

#### Restricted benefit

Patients requiring administration of fluorouracil by intravenous infusion

# Injection

| 7234R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 5500 mg     | 11          | ..         | *164.37 | 40.30    | DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)<br>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) |

### ■ FLUOROURACIL

#### Restricted benefit

Patients requiring administration of fluorouracil by intravenous injection

# Injection

| 7239B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 1000 mg     | 23          | ..         | *132.01 | 40.30    | DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)<br>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) |

### ■ GEMCITABINE

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

# Injection

| 7246J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                      |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------|
|       | 3000 mg     | 17          | ..         | *188.75 | 40.30    | DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial) |

DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

## PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

### *Vinca alkaloids and analogues*

#### ■ VINBLASTINE

##### Injection

| 7261E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                           |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------|
|       | 20 mg       | 17          | ..         | *199.18 | 40.30    | Hospira Pty Limited [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials) |

#### ■ VINCRISTINE

##### Injection

| 7262F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                      |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------|
|       | 2 mg        | 7           | ..         | *142.90 | 40.30    | Hospira Pty Limited [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials) |

#### ■ VINOIRELBINE

##### Injection

| 7263G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                              |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 70 mg       | 7           | ..         | *196.71 | 40.30    | Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial)<br>Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial)<br>Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial)<br>Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial) |

### *Podophyllotoxin derivatives*

#### ■ ETOPOSIDE

##### Injection

| 7237X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 440 mg      | 14          | ..         | *321.02 | 40.30    | Etopophos [BQ] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial)<br>Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)<br>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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                       |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------------------------------------|
|       | 55 mg       | 5           | ..         | *3014.72 | 40.30    | Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack) |

#### ■ 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                       |
|--------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 250 mg      | 5           | ..         | *222.66 | 40.30    | DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial)<br>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)  
 Docetaxel Sandoz [SZ] (docetaxel 80 mg/8 mL injection, 8 mL vial)

## ■ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

### Authority required (STREAMLINED)

**6106**

Metastatic breast cancer

### Authority required (STREAMLINED)

**6119**

HER2 positive breast cancer

### Injection

| 7270P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                         |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------|
|       | 580 mg      | 5           | ..         | *2445.32 | 40.30    | Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial) |

## ■ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

**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.

### Injection

| 10150F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                         |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------|
|        | 275 mg      | 11          | ..         | *1285.07 | 40.30    | Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial) |

## ■ PACLITAXEL

### Injection

| 7254T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 450 mg      | 3           | ..         | *200.34 | 40.30    | Anzatax [PF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)<br>Anzatax [PF] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Anzatax [PF] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 30 mg/5 mL injection, 5 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel Ebewe [SZ] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Paclitaxel Ebewe [SZ] (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)<br>Paclitaxel Ebewe [SZ] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel Kabi [PK] (paclitaxel 30 mg/5 mL injection, 5 mL vial)<br>Paclitaxel Kabi [PK] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxin [TB] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)<br>Paclitaxin [TB] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Paclitaxin [TB] (paclitaxel 30 mg/5 mL injection, 5 mL vial)<br>Paclitaxin [TB] (paclitaxel 300 mg/50 mL injection, 50 mL vial) |

## CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

## Anthracyclines and related substances

## ■ DOXORUBICIN

## Injection/intravesical

| 7229L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 135 mg      | 11          | ..         | *176.69 | 40.30    | Adriamycin [PF] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)<br>Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) |

## ■ 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 100 mg      | 5           | ..         | *1203.70 | 40.30    | Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)<br>Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)<br>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)<br>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial) |

## ■ EPIRUBICIN

## Injection/intravesical

| 7231N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 220 mg      | 5           | ..         | *206.17 | 40.30    | Epirube [TB] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Epirube [TB] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)<br>Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Epirubicin ACT [JU] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial)<br>Epirubicin ACT [JU] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Epirubicin ACT [JU] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)<br>Pharmorubicin [PF] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Pharmorubicin [PF] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) |

## ■ IDARUBICIN

Restricted benefit

Acute myelogenous leukaemia (AML)

## Injection

| 7247K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                        |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------|
|       | 30 mg       | 5           | ..         | *258.80 | 40.30    | Idarubicin Ebewe [SZ] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) |

Zavedos Solution [PF] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial)  
Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)

## ■ MITOZANTRONE

### Injection

| 7252Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                        |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 30 mg       | 5           | ..         | *218.72 | 40.30    | Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial)<br>Onkotrone [BX] (mitozantrone 20 mg/10 mL injection, 10 mL vial)<br>Onkotrone [BX] (mitozantrone 25 mg/12.5 mL injection, 12.5 mL vial) |

### Other cytotoxic antibiotics

## ■ BLEOMYCIN SULFATE

### Restricted benefit

Germ cell neoplasms

### Restricted benefit

Lymphoma

### Injection

| 11701W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                        |
|--------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------|
|        | 30000 iu    | 11          | ..         | *168.08 | 40.30    | Bleomycin for Injection, USP [QY] (bleomycin sulfate 15 000 international units injection, 1 vial) |

### Injection

| 7244G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                          |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 30000 iu    | 11          | ..         | *168.08 | 40.30    | Bleo 15K [JU] (bleomycin sulfate 15 000 international units injection, 1 vial)<br>CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial)<br>Hospira Pty Limited [PF] (bleomycin sulfate 15 000 international units injection, 1 vial) |

## OTHER ANTINEOPLASTIC AGENTS

### Platinum compounds

## ■ CARBOPLATIN

### Injection

| 7222D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                        |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 900 mg      | 5           | ..         | *196.80 | 40.30    | Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial)<br>Hospira Pty Limited [PF] (carboplatin 150 mg/15 mL injection, 15 mL vial)<br>Hospira Pty Limited [PF] (carboplatin 450 mg/45 mL injection, 45 mL vial) |

## ■ CISPLATIN

### Injection

| 7224F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                          |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 220 mg      | 14          | ..         | *170.79 | 40.30    | Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial)<br>Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial)<br>Hospira Pty Limited [PF] (cisplatin 100 mg/100 mL injection, 100 mL vial)<br>Hospira Pty Limited [PF] (cisplatin 50 mg/50 mL injection, 50 mL vial) |

## ■ OXALIPLATIN

### Injection

| 7253R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 300 mg      | 11          | ..         | *184.87 | 40.30    | DBL Oxaliplatin Concentrate [PF] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)<br>Oxaliplatin Accord [OC] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)<br>Oxaliplatin SUN [RA] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) |

Oxaliplatin SUN [RA] (oxaliplatin 200 mg/40 mL injection, 40 mL vial)  
 Oxaliplatin SUN [RA] (oxaliplatin 50 mg/10 mL injection, 10 mL vial)  
 Oxaliplatin SZ [HX] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)

### Monoclonal antibodies

#### ■ ATEZOLIZUMAB

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

**Note** Special Pricing Arrangements apply.

##### Authority required (STREAMLINED)

**6999**

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 treatment for this condition, **AND**
- Patient must have stable or responding disease.

##### Authority required (STREAMLINED)

**7572**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

##### **Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 April 2018, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must have stable or responding disease, **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.

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

| 11297N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------|
|        | 1200 mg     | 7           | ..         | *7705.79 | 40.30    | Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial) |

#### ■ ATEZOLIZUMAB

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

**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** Special Pricing Arrangements apply.

##### Authority required (STREAMLINED)

**7539**

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 this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy.

#### Injection

| 11309F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------|
|        | 1200 mg     | 5           | ..         | *7705.79 | 40.30    | Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial) |

#### ■ 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------|
|        | 1200 mg     | 8           | ..         | *8382.98 | 40.30    | Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial) |

#### ■ AVELUMAB

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

**Note** Special Pricing Arrangements apply.

##### Authority required (STREAMLINED)

**8856**

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 total of 12 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.

#### Injection

| 11685B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------|
|        | 1200 mg     | 11          | ..         | *8382.98 | 40.30    | Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial) |

#### ■ 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.

#### Injection

| 10114H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 900 mg      | 11          | ..         | *3206.74 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

#### ■ 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.

#### Injection

| 10120P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------|
|        | 900 mg      | 5           | ..         | *3206.74 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) |

## ■ 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.

### 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

| 10885X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 1800 mg     | 7           | ..         | *6288.66 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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.

### Injection

| 11727F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 1800 mg     | 3           | ..         | *6288.66 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

### ■ 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **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).

## Injection

| 11731K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 1800 mg     | 5           | ..         | *6288.66 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

## ■ 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.

## Injection

| 7243F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 900 mg      | 11          | ..         | *3206.74 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

## ■ 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

### Authority required

Acute lymphoblastic leukaemia (ALL)

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**
- The condition must be Philadelphia chromosome negative, **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**
- 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;
- (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) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

### **Injection**

| 11116C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                      |
|--------|-------------|-------------|------------|-----------|----------|------------------------------------------------------------------------------------------------------------------|
|        | 651 mcg     | ..          | ..         | *70815.38 | 40.30    | Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack) |

## ■ 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 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).

### Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment - balance of supply

### 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**
- The condition must be Philadelphia chromosome negative, **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.

### Injection

| 11119F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                       |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------------------------------------------------------------|
|        | 784 mcg     | ..          | ..         | *82597.14 | 40.30    | Blinicyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack) |

## ■ 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 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** 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).

#### Authority required

Acute lymphoblastic leukaemia (ALL)

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

| 11115B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                       |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------------------------------------------------------------|
|        | 784 mcg     | 2           | ..         | *82597.14 | 40.30    | Blinicyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack) |

## ■ 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 11          | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ 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

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.

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

### Injection

| 11067L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 11          | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

### ■ 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

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.

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)

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

### Injection

| 11086L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 11          | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

### ■ BRENTUXIMAB VEDOTIN

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 3           | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ BRENTUXIMAB VEDOTIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
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

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;
- (b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and
- (c) a signed patient acknowledgement.

### Injection

| 11080E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 3           | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ BRENTUXIMAB VEDOTIN

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
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

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;
- (b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and
- (c) a signed patient acknowledgement.

### Injection

| 11089P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 3           | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
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**

| 11651F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 180 mg      | 3           | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

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

**Authority required**

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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 180 mg      | 11          | ..         | *19999.22 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

▪ **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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 550 mg      | 5           | ..         | *1898.65 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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**

| 7223E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 880 mg      | ..          | ..         | *2785.57 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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**

| 7242E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 880 mg      | ..          | ..         | *2785.57 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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.

**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**

| 10265G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 550 mg      | 18          | ..         | *1898.65 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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.

**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.

### **Injection**

| 7273T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 550 mg      | 11          | ..         | *1898.65 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial) |

## ■ 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** 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** 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).

**Authority required**

Acute lymphoblastic leukaemia (ALL)

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 m<sup>2</sup> for all doses within a treatment cycle  
Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.

**Injection**

| 11668D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|-----------|----------|--------------------------------------------------------------|
|        | 2820 mcg    | 4           | ..         | *40003.13 | 40.30    | Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial) |

■ **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** 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** An increase in the maximum number of repeats of up to 4 will be allowed for completion of consolidation therapy.

**Authority required**

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Grandfather treatment

**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 2 lines of salvage therapy, **AND**
- The condition must be Philadelphia chromosome negative, **AND**
- The condition must be CD22-positive, **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 May 2019, **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.

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

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

Patients who have received up to three treatment cycles as induction therapy with this drug for this condition prior to 1 May 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 one treatment cycle as consolidation therapy with this drug for this condition prior to 1 May 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 3 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;
- (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 inotuzumab ozogamicin dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised inotuzumab ozogamicin will be required for completion of induction or consolidation therapy; and
- (5) date of latest chemotherapy prior to receiving non-PBS subsidised inotuzumab ozogamicin, and if it was the initial chemotherapy regimen or for salvage therapy and what line of salvage; and
- (6) a copy of bone marrow biopsy report prior to receiving non-PBS subsidised inotuzumab ozogamicin.

### Injection

|        |             |             |            |           |          |                                                              |
|--------|-------------|-------------|------------|-----------|----------|--------------------------------------------------------------|
| 11689F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                  |
|        | 3384 mcg    | 1           | ..         | *53295.90 | 40.30    | Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial) |

### ■ 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 m<sup>2</sup>, and the second prescription for two doses at a dose no higher than 0.5mg per m<sup>2</sup>. 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Acute lymphoblastic leukaemia (ALL)

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**
- The condition must be Philadelphia chromosome negative, **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 m<sup>2</sup> for the first dose of a treatment cycle (Day 1), and 0.5mg per m<sup>2</sup> 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.

**Injection**

| 11673J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|-----------|----------|--------------------------------------------------------------|
|        | 3384 mcg    | 2           | ..         | *53295.90 | 40.30    | Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial) |

**■ IPILIMUMAB**

**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)****8569**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- Patient must have received less than 4 doses of combined therapy with ipilimumab and nivolumab as induction therapy for this condition prior to 1 March 2019, **AND**
- The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- The condition must not have previously been treated prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- The treatment must be in combination with PBS-subsidised-treatment with nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction 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.

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**

| 11647B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|-----------|----------|------------------------------------------------------------|
|        | 120 mg      | 2           | ..         | *17238.86 | 40.30    | Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial) |

**■ IPILIMUMAB**

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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)

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 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|-----------|----------|------------------------------------------------------------|
|        | 120 mg      | 3           | ..         | *17238.86 | 40.30    | Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial) |

**■ IPILIMUMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6562**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
  - Patient must not have received prior treatment with ipilimumab, **AND**
  - The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.
- The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Note** For patients who commence therapy with ipilimumab:

- 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;
- 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.
- An initial objective response to treatment is defined as either:
- 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
  - 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 increase 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)**

**8206**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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.

**Authority required (STREAMLINED)**

**8142**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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.

**Authority required (STREAMLINED)**

**8178**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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.

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.

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

**Authority required (STREAMLINED)**

**8180**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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.

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.

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

**Injection**

| 2638W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                               |
|-------|-------------|-------------|------------|-----------|----------|---------------------------------------------------------------------------------------------------------------------------|
|       | 360 mg      | 3           | ..         | *45762.26 | 40.30    | Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)<br>Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial) |

▪ **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**
- 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

| 11157F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

## ■ 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)

Treatment Phase: Maintenance treatment

#### **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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

## ■ 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

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.

### Authority required (STREAMLINED)

**9214**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Maintenance treatment

#### **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

| 10748Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

## ■ 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)

**9331**

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 this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- The condition 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**

| 11143L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

■ **NIVOLUMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9217**

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 treatment 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)**

**9311**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 August 2017, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have a WHO performance status of 0 or 1.

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**

| 11152Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

■ **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)**

**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

| 11434T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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)

##### 9219

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 1

#### **Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor) unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 dose of 3 mg/kg or 240 mg every two weeks or 480 mg every four weeks. 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.

#### Authority required (STREAMLINED)

##### 9320

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 2

#### **Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 dose of 3 mg/kg or 240 mg every two weeks or 480 mg every four weeks. 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

| 10775D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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

| 11159H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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

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.

#### Authority required (STREAMLINED)

#### 9253

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

Treatment Phase: Grandfather treatment

#### Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2018, **AND**
- Patient must have had a WHO performance status of 0 or 1, **AND**
- The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition, **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.

**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

| 11425H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10232.76 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ NIVOLUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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

| 11627Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 360 mg      | 3           | ..         | *7705.78 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ NIVOLUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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)

**8571**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Grandfather patients

#### **Clinical criteria:**

- Patient must have received less than 4 doses of combined therapy with ipilimumab and nivolumab as induction therapy for this condition prior to 1 March 2019; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 March 2019, **AND**
- The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- The condition must not have previously been treated prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition; OR
- The treatment must be as monotherapy as maintenance 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.

Maintenance treatment with nivolumab must not exceed a maximum dose of 3 mg per kg every 2 weeks.

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.

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

### Injection

| 11635J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 360 mg      | 2           | ..         | *7705.78 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ NIVOLUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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)

**8182**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

#### **Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
  - Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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.
- The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)****8141**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)****8146**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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; OR
- The treatment must be as monotherapy as maintenance 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. Maintenance treatment with nivolumab must not exceed a maximum dose of 3 mg per kg every 2 weeks. 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. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)****8220**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**

- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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; OR
- The treatment must be as monotherapy as maintenance 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. Maintenance treatment with nivolumab must not exceed a maximum dose of 3 mg per kg every 2 weeks.

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.

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

#### Injection

| 11532Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 120 mg      | 3           | ..         | *2651.81 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 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

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           | ..         | *5491.92 | 40.30    | 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.

**Injection**

| 11473W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 5           | ..         | *5491.92 | 40.30    | 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**

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 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**

| 11456Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 9           | ..         | *5491.92 | 40.30    | 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: 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.
- 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.

**Injection**

| 11460E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 7           | ..         | *5491.92 | 40.30    | 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.

**Note** Obinutuzumab is not to be used as monotherapy or in combination with anti-cancer drugs other than chlorambucil.

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

**Authority required (STREAMLINED)**

**8184**

Chronic lymphocytic leukaemia (CLL)

**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**

| 10418H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 7           | ..         | *5491.92 | 40.30    | 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**

| 10069Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                    |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------------|
|        | 720 mg      | 5           | ..         | *3970.90 | 40.30    | Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)<br>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

| 10508C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                    |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------------|
|        | 720 mg      | 9           | ..         | *3970.90 | 40.30    | Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)<br>Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial) |

## ■ PEMBROLIZUMAB

**Note** Special Pricing Arrangements apply.

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

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

**9044**

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, **AND**
- The treatment must not exceed a maximum dose administered every 3 weeks fixed at 200 mg.

# Injection

| 10424P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 7           | ..         | *9169.70 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

## ■ PEMBROLIZUMAB

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

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

**9178**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 1

### **Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor) unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 6 doses administered every 3 weeks, with each maximum dose fixed at 200 mg. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

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

**9127**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 2

### **Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 6 doses administered every 3 weeks, with each maximum dose fixed at 200 mg. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

# Injection

| 10475H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 5           | ..         | *9169.70 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

## ■ 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.

### **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.
- 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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. The treatment must not exceed a total of 35 cycles in a lifetime.

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

#### **Authority required**

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment - Grandfathered patients

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with a programmed cell death 1 (PD-1) inhibitor for this condition prior to 1 May 2018, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT prior to receiving treatment with a PD-1 inhibitor for this condition; OR
- Patient must not have been suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition prior to receiving treatment with a PD-1 inhibitor 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 the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 35 cycles in a lifetime.

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.

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 for Grandfathered patients.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Injection**

| 11352L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 6           | ..         | *9169.70 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

### **■ 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.

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

#### **8563**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised treatment 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 at a maximum dose of 200 mg every 3 weeks for this condition 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)**

**8543**

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 treatment for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug for this condition.

**Authority required (STREAMLINED)**

**8542**

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

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 March 2019, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy prior to initiating treatment with this drug for this condition; 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 prior to initiating treatment with this drug for this condition; 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 prior to initiating treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug 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.

**Injection**

| 11632F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 6           | ..         | *9169.70 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

▪ **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.

**Authority required (STREAMLINED)**

**8122**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample; **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 tumour material, **AND**
- The treatment must not exceed a total of 7 doses at a maximum dose of 200 mg every 3 weeks for this condition 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)**

##### **8123**

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

Treatment Phase: Grandfathering treatment

#### **Clinical criteria:**

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 November 2018, **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 stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **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 express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample 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 in tumour material, **AND**
- The treatment must not exceed 35 doses in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks, with this drug for this condition.

**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.

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

##### **8124**

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

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 treatment for this condition, **AND**
- The treatment must not exceed 35 doses in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks, with this drug for this condition.

#### **Injection**

| 11492W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 6           | ..         | *9169.70 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

#### **■ PERTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; **OR**
- Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015, **AND**

- Patient must not have received non-PBS-subsidised treatment with trastuzumab for this condition before 1 July 2014, **AND**
- Patient must not have received prior therapy with trastuzumab emtansine or lapatinib for this condition, **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.

Authority applications for treatment must be made in writing and must include a completed authority prescription form and a copy of the signed patient acknowledgement form.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

#### Injection

| 10268K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------|
|        | 840 mg      | 1           | ..         | *6355.58 | 40.30    | Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial) |

#### ■ PERTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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

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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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. However, short treatment breaks are permitted. A patient who has a treatment break of less than 6 weeks 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. A patient who has a treatment break of more than 6 weeks in PBS-subsidised treatment with this drug is not eligible 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------|
|        | 420 mg      | 3           | ..         | *3240.20 | 40.30    | Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial) |

#### ■ PERTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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:
  - (i) a copy 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; and
  - (ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

### Injection

| 10334X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------|
|        | 840 mg      | ..          | ..         | *6355.58 | 40.30    | Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial) |

## ▪ 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).

### Injection

| 7257Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                       |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------|
|       | 800 mg      | 7           | ..         | *2630.58 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) |
|       |             |             |            |          |          | Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)      |

## ▪ RITUXIMAB

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

### 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.

### Injection

| 7258B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                       |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------|
|       | 800 mg      | 7           | ..         | *2630.58 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) |
|       |             |             |            |          |          | Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)      |

## ▪ 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.

### Injection

| 7259C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                       |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------|
|       | 800 mg      | 5           | ..         | *2630.58 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) |
|       |             |             |            |          |          | Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)      |

### ■ 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.

### Injection

| 10193L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                       |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------|
|        | 800 mg      | 11          | ..         | *2630.58 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) |
|        |             |             |            |          |          | Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)      |

### ■ TRASTUZUMAB

#### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

#### **Clinical criteria:**

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone 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**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

#### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

#### **Clinical criteria:**

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **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.

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

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

(a) a completed authority prescription form; and

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

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

## Injection

| 7264H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 500 mg      | ..          | ..         | *1936.15 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

### Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone 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**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

### Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **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.

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

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

(a) a completed authority prescription form; and

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

- a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
- a copy of the signed patient acknowledgement form.

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## Injection

| 7266K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 1000 mg     | ..          | ..         | *3774.50 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, **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), at 3 monthly intervals during treatment.

**Injection**

| 10381J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 1000 mg     | 3           | ..         | *3774.50 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

▪ **TRASTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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**

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**
- 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, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**Injection**

| 10383L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 750 mg      | 3           | ..         | *2801.25 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

▪ **TRASTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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**
- 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 a copy 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 patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**Injection**

| 10402L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                   |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------|
|        | 1000 mg     | ..          | ..         | *3774.50 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial) |

## ■ 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

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 cisplatin and capecitabine; OR
- Patient must commence treatment in combination with cisplatin 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.

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

(a) a completed authority prescription form; and

(b) a completed Metastatic (Stage IV) HER2 positive adenocarcinoma of stomach or gastro-oesophageal junction authority application form which includes confirmation that the patient has Stage IV disease and a copy of the pathology report from an Approved Pathology Authority confirming evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated in tumour material by both (i) immunohistochemistry (IHC) 2+ or IHC 3+ AND (ii) in situ hybridisation (ISH) results based on both more than 6 copies of HER2 AND the ratio of HER2: chromosome 17 being more than 2 in the same tumour tissue sample

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment

### Injection

| 10589H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 1000 mg     | ..          | ..         | *3774.50 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised with one exception: where a patient has a break in therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose up to a maximum of 1000 mg.

**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

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

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 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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

### Injection

| 10597R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                           |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------|
|        | 750 mg      | 3           | ..         | *2801.25 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) |

Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)  
Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)

## ■ TRASTUZUMAB

- Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Locally advanced HER2 positive breast cancer  
Treatment Phase: Continuing treatment (weekly regimen)

### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

### Authority required

Early HER2 positive breast cancer  
Treatment Phase: Continuing treatment (weekly regimen)

### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

## Injection

| 7265J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 250 mg      | 9           | ..         | *1071.05 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

- Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Locally advanced HER2 positive breast cancer  
Treatment Phase: Continuing treatment (3 weekly regimen)

### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
  - The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
  - Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
- Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

#### **Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
  - The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
  - Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
- Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

### **Injection**

| 7267L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 750 mg      | 3           | ..         | *2801.25 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

### **▪ TRASTUZUMAB EMTANSINE**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

#### **Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; **OR**
- Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015; **OR**
- Patient must have received PBS-subsidised lapatinib for this condition before 1 July 2015, **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.

Authority applications for treatment must be made in writing and must include a completed authority prescription form and a copy of the signed patient acknowledgement form.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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**
- 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) a copy 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) a copy of the signed patient acknowledgement form;
  - (iii) dates of treatment with trastuzumab and pertuzumab; and
  - (iv) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab; or
  - (v) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during 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.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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 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 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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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.

**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**

| 10281D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                    |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------------|
|        | 450 mg      | 8           | ..         | *7788.50 | 40.30    | Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)<br>Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial) |

#### ***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.

#### **Injection**

| 10699D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                              |
|--------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------|
|        | 18 mg       | 140         | ..         | *856.42 | 40.30    | Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) |

#### **■ 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.

**Injection**

| 7241D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                              |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------|
|       | 18 mg       | 89          | ..         | *856.42 | 40.30    | Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) |

**■ 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**

| 7269N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                            |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 11          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

**■ 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.

**Injection**

| 7272R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                            |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 11          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

▪ **BORTEZOMIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7992**

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, **AND**
  - Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.
- Details of the histological diagnosis of multiple myeloma must be documented in the patient's medical records.

**Injection**

| 7275X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                          |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 15          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 1 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3 mg injection, 1 vial) |

▪ **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 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.

**Injection**

| 7274W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                          |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 19          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 1 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3 mg injection, 1 vial) |

▪ **BORTEZOMIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7963**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- Patient must be ineligible for high dose chemotherapy, **AND**
- Patient must not be receiving 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)**

**7984**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- Patient must have severe acute renal failure, **AND**
- Patient must require dialysis; OR
- Patient must be at high risk of requiring dialysis in the opinion of a nephrologist, **AND**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must not be receiving 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.

## Injection

| 7238Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                      |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------|
|       | 3000 mcg    | 31          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 1 mg injection, 1 vial) |
|       |             |             |            |          |          | Velcade [JC] (bortezomib 3 mg injection, 1 vial) |

## ■ 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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

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
- (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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                            |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 15          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

▪ **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 of the difference between involved free light chain and uninvolved free light chain; or

- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

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

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

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

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

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.

## Injection

| 7271Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                        |
|-------|-------------|-------------|------------|----------|----------|----------------------------------------------------|
|       | 3000 mcg    | 15          | ..         | *1398.50 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)   |
|       |             |             |            |          |          | Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

## ■ 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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

### 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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

**Authority required**

Multiple myeloma

Treatment Phase: Grandfathering

**Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 January 2018, **AND**
- Patient must have a documented histological diagnosis, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have had documented progressive disease after at least one prior therapy prior to commencing 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**
- Patient must have undergone or be ineligible for a stem cell transplant, **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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

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**

| 11230C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                       |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 120 mg      | 17          | ..         | *2698.22 | 40.30    | Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial)<br>Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial)<br>Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial) |

▪ **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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------|
|        | 3 mg        | 13          | ..         | *854.90 | 40.30    | Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial) |

▪ **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.

**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**

|        |             |             |            |         |          |                                                                 |
|--------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------|
| 11199K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                     |
|        | 3 mg        | 7           | ..         | *854.90 | 40.30    | Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial) |

▪ **IRINOTECAN**

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

**Injection**

|       |             |             |            |         |          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7249M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|       | 800 mg      | 11          | ..         | *190.58 | 40.30    | Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)<br>Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>IRINOTECAN ACT [JU] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>IRINOTECAN ACT [JU] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)<br>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)<br>Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)<br>Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) |

▪ **TOPOTECAN**

**Authority required (STREAMLINED)**

**6238**

Advanced metastatic ovarian cancer

**Clinical criteria:**

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

**Injection**

|       |             |             |            |         |          |                                                   |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------|
| 7260D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                       |
|       | 3500 mcg    | 17          | ..         | *157.35 | 40.30    | Hycamtin [SZ] (topotecan 4 mg injection, 5 vials) |

# Chemotherapy items for Public Hospital use

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## ■ 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

| 10760H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                   |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|        | 200 mg      | 11          | ..         | *1699.70 | 40.30    | Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial)<br>Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial) |

#### ■ CYCLOPHOSPHAMIDE

#### Injection

| 4327R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 2800 mg     | 17          | ..         | *156.76 | 40.30    | Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial)<br>Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial)<br>Endoxan [BX] (cyclophosphamide 500 mg injection, 1 vial) |

#### ■ IFOSFAMIDE

#### Injection

| 4448D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                        |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------|
|       | 4000 mg     | 19          | ..         | *281.70 | 40.30    | Holoxan [BX] (ifosfamide 1 g injection, 1 vial)<br>Holoxan [BX] (ifosfamide 2 g injection, 1 vial) |

*Nitrosoureas*

## ■ FOTEMUSTINE

### Authority required (STREAMLINED)

6288

Metastatic malignant melanoma

### Injection

| 4437M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                              |
|-------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------------------------------------------------|
|       | 220 mg      | 8           | ..         | *1939.26 | 40.30    | Muphoran [SE] (fotemustine 208 mg injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack) |

## ANTIMETABOLITES

### *Folic acid analogues*

## ■ METHOTREXATE

### Injection

| 4502Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 250 mg      | 5           | ..         | *110.56 | 40.30    | Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial)<br>Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1)<br>Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)<br>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

### Injection

| 4512L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 20000 mg    | ..          | ..         | *838.46 | 40.30    | Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials)<br>Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial)<br>Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1)<br>Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)<br>Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)<br>Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) |

## ■ PEMETREXED

### Injection

| 4600D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                             |
|-------|-------------|-------------|------------|---------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 1100 mg     | 5           | ..         | *169.35 | 40.30    | Alimta [LY] (pemetrexed 100 mg injection, 1 vial)<br>Alimta [LY] (pemetrexed 500 mg injection, 1 vial)<br>DBL Pemetrexed [PF] (pemetrexed 1 g injection, 1 vial)<br>DBL Pemetrexed [PF] (pemetrexed 100 mg injection, 1 vial)<br>DBL Pemetrexed [PF] (pemetrexed 500 mg injection, 1 vial)<br>Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial)<br>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-DRLA [RZ] (pemetrexed 100 mg injection, 1 vial)  
 Pemetrexed DRLA [RZ] (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)

## ■ 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

| 11272G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                               |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------|
|        | 80 mg       | 11          | ..         | *4445.06 | 40.30    | Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL 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

| 11293J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                               |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------|
|        | 80 mg       | 5           | ..         | *4445.06 | 40.30    | Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial) |

## ■ 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

| 4610P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                       |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------|
|       | 7 mg        | 8           | ..         | *1127.90 | 40.30    | Tomudex [PF] (raltitrexed 2 mg injection, 1 vial) |

## Purine analogues

## ■ CLADRIBINE

### Authority required (STREAMLINED)

**6265**

Hairy cell leukaemia

### Injection

| 4326Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                              |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------|
|       | 17 mg       | 6           | ..         | *1125.50 | 40.30    | Leustatin [JC] (cladribine 10 mg/10 mL injection, 10 mL vial)<br>Litak [OA] (cladribine 10 mg/5 mL injection, 5 mL vial) |

## ■ 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

| 4393F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 55 mg       | 29          | ..         | *148.74 | 40.30    | Fludarabine ACT [JU] (fludarabine phosphate 50 mg injection, 1 vial)<br>Fludarabine AMNEAL [JU] (fludarabine phosphate 50 mg injection, 1 vial)<br>Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials) |

## Pyrimidine analogues

### ■ CYTARABINE

## Injection

| 4357H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                      |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------|
|       | 7000 mg     | 15          | ..         | *883.06 | 40.30    | Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials) |

### ■ FLUOROURACIL

#### Restricted benefit

Patients requiring administration of fluorouracil by intravenous infusion

## Injection

| 4394G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 5500 mg     | 11          | ..         | *124.06 | 40.30    | DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)<br>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) |

### ■ FLUOROURACIL

#### Restricted benefit

Patients requiring administration of fluorouracil by intravenous injection

## Injection

| 4431F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 1000 mg     | 23          | ..         | *92.15  | 40.30    | DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)<br>Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)<br>Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial)<br>Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) |

### ■ GEMCITABINE

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

## Injection

| 4439P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                      |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------|
|       | 3000 mg     | 17          | ..         | *148.11 | 40.30    | DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial) |

DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

**PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS**

*Vinca alkaloids and analogues*

■ **VINBLASTINE**

**Injection**

| 4618C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                           |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------------------------------|
|       | 20 mg       | 17          | ..         | *158.40 | 40.30    | Hospira Pty Limited [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials) |

■ **VINCRISTINE**

**Injection**

| 4619D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                      |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------|
|       | 2 mg        | 7           | ..         | *102.90 | 40.30    | Hospira Pty Limited [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials) |

■ **VINORELBINE**

**Injection**

| 4620E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                              |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 70 mg       | 7           | ..         | *155.96 | 40.30    | Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial)<br>Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial)<br>Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial)<br>Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial) |

*Podophyllotoxin derivatives*

■ **ETOPOSIDE**

**Injection**

| 4428C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 440 mg      | 14          | ..         | *278.56 | 40.30    | Etopophos [BQ] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial)<br>Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)<br>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**

| 4376H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                       |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------------------------------------|
|       | 55 mg       | 5           | ..         | *2935.06 | 40.30    | Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack) |

■ **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**

| 10148D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                       |
|--------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 250 mg      | 5           | ..         | *181.54 | 40.30    | DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial)<br>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)  
 Docetaxel Sandoz [SZ] (docetaxel 80 mg/8 mL injection, 8 mL vial)

## ■ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

### Authority required (STREAMLINED)

**6106**

Metastatic breast cancer

### Authority required (STREAMLINED)

**6119**

HER2 positive breast cancer

### Injection

| 4531L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                         |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------|
|       | 580 mg      | 5           | ..         | *2373.52 | 40.30    | Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial) |

## ■ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

**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.

### Injection

| 10165B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                         |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------|
|        | 275 mg      | 11          | ..         | *1229.29 | 40.30    | Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial) |

## ■ PACLITAXEL

### Injection

| 4567J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 450 mg      | 3           | ..         | *159.54 | 40.30    | Anzatax [PF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)<br>Anzatax [PF] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Anzatax [PF] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 30 mg/5 mL injection, 5 mL vial)<br>Paclitaxel ACT [JU] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel Ebewe [SZ] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Paclitaxel Ebewe [SZ] (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)<br>Paclitaxel Ebewe [SZ] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxel Kabi [PK] (paclitaxel 30 mg/5 mL injection, 5 mL vial)<br>Paclitaxel Kabi [PK] (paclitaxel 300 mg/50 mL injection, 50 mL vial)<br>Paclitaxin [TB] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)<br>Paclitaxin [TB] (paclitaxel 150 mg/25 mL injection, 25 mL vial)<br>Paclitaxin [TB] (paclitaxel 30 mg/5 mL injection, 5 mL vial)<br>Paclitaxin [TB] (paclitaxel 300 mg/50 mL injection, 50 mL vial) |

**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES**

*Anthracyclines and related substances*

▪ **DOXORUBICIN**

**Injection/intravesical**

| 4361M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 135 mg      | 11          | ..         | *136.21 | 40.30    | Adriamycin [PF] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)<br>Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) |

▪ **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**

| 4364Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 100 mg      | 5           | ..         | *1149.04 | 40.30    | Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)<br>Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)<br>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial)<br>Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial) |

▪ **EPIRUBICIN**

**Injection/intravesical**

| 4375G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 220 mg      | 5           | ..         | *165.29 | 40.30    | Epirube [TB] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Epirube [TB] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)<br>Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Epirubicin ACT [JU] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial)<br>Epirubicin ACT [JU] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Epirubicin ACT [JU] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)<br>Pharmorubicin [PF] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)<br>Pharmorubicin [PF] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) |

▪ **IDARUBICIN**

Restricted benefit

Acute myelogenous leukaemia (AML)

**Injection**

| 4440Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                        |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------|
|       | 30 mg       | 5           | ..         | *217.18 | 40.30    | Idarubicin Ebewe [SZ] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) |

Zavedos Solution [PF] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial)  
Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)

## ■ MITOZANTRONE

### Injection

| 4514N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                        |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 30 mg       | 5           | ..         | *177.66 | 40.30    | Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial)<br>Onkotrone [BX] (mitozantrone 20 mg/10 mL injection, 10 mL vial)<br>Onkotrone [BX] (mitozantrone 25 mg/12.5 mL injection, 12.5 mL vial) |

### Other cytotoxic antibiotics

## ■ BLEOMYCIN SULFATE

### Restricted benefit

Germ cell neoplasms

### Restricted benefit

Lymphoma

### Injection

| 11704B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                        |
|--------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------|
|        | 30000 iu    | 11          | ..         | *127.72 | 40.30    | Bleomycin for Injection, USP [QY] (bleomycin sulfate 15 000 international units injection, 1 vial) |

### Injection

| 4433H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                          |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 30000 iu    | 11          | ..         | *127.72 | 40.30    | Bleo 15K [JU] (bleomycin sulfate 15 000 international units injection, 1 vial)<br>CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial)<br>Hospira Pty Limited [PF] (bleomycin sulfate 15 000 international units injection, 1 vial) |

## OTHER ANTINEOPLASTIC AGENTS

### Platinum compounds

## ■ CARBOPLATIN

### Injection

| 4309T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                        |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 900 mg      | 5           | ..         | *156.04 | 40.30    | Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial)<br>Hospira Pty Limited [PF] (carboplatin 150 mg/15 mL injection, 15 mL vial)<br>Hospira Pty Limited [PF] (carboplatin 450 mg/45 mL injection, 45 mL vial) |

## ■ CISPLATIN

### Injection

| 4319H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                          |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 220 mg      | 14          | ..         | *130.40 | 40.30    | Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial)<br>Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial)<br>Hospira Pty Limited [PF] (cisplatin 100 mg/100 mL injection, 100 mL vial)<br>Hospira Pty Limited [PF] (cisplatin 50 mg/50 mL injection, 50 mL vial) |

## ■ OXALIPLATIN

### Injection

| 4542C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 300 mg      | 11          | ..         | *144.28 | 40.30    | DBL Oxaliplatin Concentrate [PF] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)<br>Oxaliplatin Accord [OC] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)<br>Oxaliplatin SUN [RA] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) |

Oxaliplatin SUN [RA] (oxaliplatin 200 mg/40 mL injection, 40 mL vial)  
 Oxaliplatin SUN [RA] (oxaliplatin 50 mg/10 mL injection, 10 mL vial)  
 Oxaliplatin SZ [HX] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)

**Monoclonal antibodies**

▪ **ATEZOLIZUMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6999**

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 treatment for this condition, **AND**
- Patient must have stable or responding disease.

**Authority required (STREAMLINED)**

**7572**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 April 2018, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must have stable or responding disease, **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.

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**

| 11277M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------|
|        | 1200 mg     | 7           | ..         | *7561.36 | 40.30    | Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial) |

▪ **ATEZOLIZUMAB**

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

**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** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7539**

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 this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy.

**Injection**

| 11284X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------|
|        | 1200 mg     | 5           | ..         | *7561.36 | 40.30    | Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial) |

▪ **AVELUMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**8856**

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 total of 12 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.

### Injection

| 11671G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------|
|        | 1200 mg     | 11          | ..         | *8229.22 | 40.30    | Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial) |

### ■ 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

| 11695M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------|
|        | 1200 mg     | 8           | ..         | *8229.22 | 40.30    | Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial) |

### ■ 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.

### Injection

| 10115J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 900 mg      | 5           | ..         | *3124.43 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

### ■ 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.

### Injection

| 10121Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------|
|        | 900 mg      | 11          | ..         | *3124.43 | 40.30    | 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.

### 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.

### 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

| 10881Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 1800 mg     | 7           | ..         | *6163.80 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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.

## Injection

| 11749J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 1800 mg     | 3           | ..         | *6163.80 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

## ■ 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### 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).

## Injection

| 11745E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 1800 mg     | 5           | ..         | *6163.80 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

## ■ 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.

## Injection

| 4400N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 900 mg      | 11          | ..         | *3124.43 | 40.30    | Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)<br>Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial) |

## ■ 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

### Authority required

Acute lymphoblastic leukaemia (ALL)

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**
- The condition must be Philadelphia chromosome negative, **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**
- 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;
- (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) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

### Injection

| 11118E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                      |
|--------|-------------|-------------|------------|-----------|----------|------------------------------------------------------------------------------------------------------------------|
|        | 651 mcg     | ..          | ..         | *69799.54 | 40.30    | Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack) |

## ■ 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 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).

### Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment - balance of supply

### 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**
- The condition must be Philadelphia chromosome negative, **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.

### Injection

| 11120G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                       |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------------------------------------------------------------|
|        | 784 mcg     | ..          | ..         | *81418.62 | 40.30    | Blinicyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack) |

### ■ 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 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** 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).

#### Authority required

Acute lymphoblastic leukaemia (ALL)

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

| 11117D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                       |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------------------------------------------------------------|
|        | 784 mcg     | 2           | ..         | *81418.62 | 40.30    | Blinicyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack) |

### ■ 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

| 10171H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 11          | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

### ■ 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

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

### Injection

|        |             |             |            |           |          |                                                             |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
| 11087M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|        | 200 mg      | 11          | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

### ■ 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

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.

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)

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

### Injection

|        |             |             |            |           |          |                                                             |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
| 11096B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|        | 200 mg      | 11          | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

### ■ BRENTUXIMAB VEDOTIN

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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 completed authority prescription form; and
- a completed Systemic anaplastic large cell lymphoma Brentuximab PBS Authority Application - Supporting Information Form which includes the following:
  - a histology report including evidence of the tumour's CD30 positivity;
  - The date of initial diagnosis of systemic anaplastic large cell lymphoma;
  - Dates of commencement and completion of front-line curative intent chemotherapy; and
  - 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

|        |             |             |            |           |          |                                                             |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
| 10166C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|        | 200 mg      | 3           | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ BRENTUXIMAB VEDOTIN

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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

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;
  - (b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and
  - (c) a signed patient acknowledgement.

### Injection

| 11073T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 3           | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ BRENTUXIMAB VEDOTIN

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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

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;
  - (b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and
  - (c) a signed patient acknowledgement.

### Injection

| 11079D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 200 mg      | 3           | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

## ■ 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
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**

| 11660Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 180 mg      | 3           | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

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

#### **Authority required**

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**

| 11664X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                 |
|--------|-------------|-------------|------------|-----------|----------|-------------------------------------------------------------|
|        | 180 mg      | 11          | ..         | *19685.06 | 40.30    | Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial) |

#### **■ 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           | ..         | *1834.40 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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      | ..          | ..         | *2709.08 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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**

| 4436L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 880 mg      | ..          | ..         | *2709.08 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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.

**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**

| 10262D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|        | 550 mg      | 18          | ..         | *1834.40 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>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.

**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.

### **Injection**

| 4731B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                  |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------------------------------|
|       | 550 mg      | 11          | ..         | *1834.40 | 40.30    | Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)<br>Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial) |

## ■ 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** 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** An increase in the maximum number of repeats of up to 4 will be allowed for completion of consolidation therapy.

**Authority required**

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Grandfather treatment

**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 2 lines of salvage therapy, **AND**
- The condition must be Philadelphia chromosome negative, **AND**
- The condition must be CD22-positive, **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 May 2019, **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.

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

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

Patients who have received up to three treatment cycles as induction therapy with this drug for this condition prior to 1 May 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 one treatment cycle as consolidation therapy with this drug for this condition prior to 1 May 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 3 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;
- (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 inotuzumab ozogamicin dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised inotuzumab ozogamicin will be required for completion of induction or consolidation therapy; and
- (5) date of latest chemotherapy prior to receiving non-PBS subsidised inotuzumab ozogamicin, and if it was the initial chemotherapy regimen or for salvage therapy and what line of salvage; and
- (6) a copy of bone marrow biopsy report prior to receiving non-PBS subsidised inotuzumab ozogamicin.

**Injection**

| 11674K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|-----------|----------|--------------------------------------------------------------|
|        | 3384 mcg    | 1           | ..         | *52522.02 | 40.30    | Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial) |

**■ 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** 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** 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).

**Authority required**

Acute lymphoblastic leukaemia (ALL)

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 m<sup>2</sup> for all doses within a treatment cycle
- Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.

**Injection**

| 11680R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|-----------|----------|--------------------------------------------------------------|
|        | 2820 mcg    | 4           | ..         | *39412.78 | 40.30    | Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial) |

**■ 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 m<sup>2</sup>, and the second prescription for two doses at a dose no higher than 0.5mg per m<sup>2</sup>. 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acute lymphoblastic leukaemia (ALL)  
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**
- The condition must be Philadelphia chromosome negative, **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 m<sup>2</sup> for the first dose of a treatment cycle (Day 1), and 0.5mg per m<sup>2</sup> 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.

## Injection

| 11696N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|-----------|----------|--------------------------------------------------------------|
|        | 3384 mcg    | 2           | ..         | *52522.02 | 40.30    | Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial) |

### ■ IPILIMUMAB

**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)

**8569**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment - Grandfather patients

#### **Clinical criteria:**

- Patient must have received less than 4 doses of combined therapy with ipilimumab and nivolumab as induction therapy for this condition prior to 1 March 2019, **AND**
- The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- The condition must not have previously been treated prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
- The treatment must be in combination with PBS-subsidised-treatment with nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction 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.

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

| 11641Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|-----------|----------|------------------------------------------------------------|
|        | 120 mg      | 2           | ..         | *16962.82 | 40.30    | Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial) |

### ■ IPILIMUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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)

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 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

| 11628B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|-----------|----------|------------------------------------------------------------|
|        | 120 mg      | 3           | ..         | *16962.82 | 40.30    | Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial) |

### ■ IPILIMUMAB

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

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

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**6562**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
  - Patient must not have received prior treatment with ipilimumab, **AND**
  - The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.
- The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Note** For patients who commence therapy with ipilimumab:

- (i) Decisions concerning efficacy should await completion of the entire induction regimen (four doses) and should be made in conjunction with established criteria for immunological responses. However induction may be ceased or delayed if symptomatic progressive disease or intolerable adverse events occur and if, in the opinion of the clinician, continuation of treatment poses a risk to the patient;
- (ii) Tumour responses may occur beyond the initial 12 week induction phase and evaluation for potential later responses should be undertaken regularly for the first year.

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**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 increase 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)**

**8206**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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.

**Authority required (STREAMLINED)**

**8142**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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.

**Authority required (STREAMLINED)**

**8178**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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.

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.

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

**Authority required (STREAMLINED)**

**8180**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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.

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.

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

**Injection**

| 2641B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                               |
|-------|-------------|-------------|------------|-----------|----------|---------------------------------------------------------------------------------------------------------------------------|
|       | 360 mg      | 3           | ..         | *45092.42 | 40.30    | Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)<br>Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial) |

▪ **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**
- 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

| 11160J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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)

Treatment Phase: Maintenance treatment

#### **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

| 11642R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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

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.

#### Authority required (STREAMLINED)

##### **9214**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Maintenance treatment

#### **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

| 10745M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ NIVOLUMAB

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

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

##### **9217**

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 treatment 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)**

**9311**

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 August 2017, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have a WHO performance status of 0 or 1.

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**

| 11153B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

■ **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)**

**9331**

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 this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- The condition 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**

| 11158G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

■ **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)**

**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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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)

##### **9219**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 1

#### **Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor) unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 dose of 3 mg/kg or 240 mg every two weeks or 480 mg every four weeks. 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.

#### Authority required (STREAMLINED)

##### **9320**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 2

#### **Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 dose of 3 mg/kg or 240 mg every two weeks or 480 mg every four weeks. 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 8           | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ 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.

#### Authority required (STREAMLINED)

**9253**

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

Treatment Phase: Grandfather treatment

#### **Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2018, **AND**
- Patient must have had a WHO performance status of 0 or 1, **AND**
- The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition, **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.

**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

| 11411N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$   | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|-----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 480 mg      | 11          | ..         | *10053.46 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

### ■ NIVOLUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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)

**8571**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Grandfather patients

#### **Clinical criteria:**

- Patient must have received less than 4 doses of combined therapy with ipilimumab and nivolumab as induction therapy for this condition prior to 1 March 2019; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 March 2019, **AND**
- The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**

- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
  - The condition must not have previously been treated prior to initiating non-PBS-subsidised induction therapy with nivolumab and ipilimumab, **AND**
  - Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
  - Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**
  - The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition; OR
  - The treatment must be as monotherapy as maintenance 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. Maintenance treatment with nivolumab must not exceed a maximum dose of 3 mg per kg every 2 weeks.
- 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.
- The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

## Injection

| 11631E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 360 mg      | 2           | ..         | *7561.36 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

## ■ NIVOLUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 360 mg      | 3           | ..         | *7561.36 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial) |

## ■ NIVOLUMAB

**Caution** Combination treatment with ipilimumab and nivolumab is associated with an increase 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)

**8182**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

#### **Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)**
**8141**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **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. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)**
**8146**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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; OR
- The treatment must be as monotherapy as maintenance 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. Maintenance treatment with nivolumab must not exceed a maximum dose of 3 mg per kg every 2 weeks. 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. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)**
**8220**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**

- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **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; OR
- The treatment must be as monotherapy as maintenance 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. Maintenance treatment with nivolumab must not exceed a maximum dose of 3 mg per kg every 2 weeks.

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.

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

#### Injection

| 11543M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                           |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------|
|        | 120 mg      | 3           | ..         | *2577.16 | 40.30    | Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)<br>Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 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

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

| 11462G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 5           | ..         | *5378.06 | 40.30    | 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.

**Injection**

| 11468N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 5           | ..         | *5378.06 | 40.30    | 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: 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.

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.

**Injection**

| 11457B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 7           | ..         | *5378.06 | 40.30    | 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**

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 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**

| 11458C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 9           | ..         | *5378.06 | 40.30    | 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.

**Note** Obinutuzumab is not to be used as monotherapy or in combination with anti-cancer drugs other than chlorambucil.

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

**Authority required (STREAMLINED)**

**8184**

Chronic lymphocytic leukaemia (CLL)

**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**

| 10407R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                |
|--------|-------------|-------------|------------|----------|----------|------------------------------------------------------------|
|        | 1000 mg     | 7           | ..         | *5378.06 | 40.30    | 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**

| 10082P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                    |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------------|
|        | 720 mg      | 5           | ..         | *3878.04 | 40.30    | Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)<br>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

| 10513H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                    |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------------|
|        | 720 mg      | 9           | ..         | *3878.04 | 40.30    | Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)<br>Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial) |

### ■ PEMBROLIZUMAB

**Note** Special Pricing Arrangements apply.

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

#### Authority required (STREAMLINED)

**9044**

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, **AND**
- The treatment must not exceed a maximum dose administered every 3 weeks fixed at 200 mg.

## Injection

| 10436G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 7           | ..         | *9005.06 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

### ■ PEMBROLIZUMAB

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

#### Authority required (STREAMLINED)

**9178**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 1

#### **Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor) unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 6 doses administered every 3 weeks, with each maximum dose fixed at 200 mg. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

#### Authority required (STREAMLINED)

**9127**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment 2

#### **Clinical criteria:**

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or 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 6 doses administered every 3 weeks, with each maximum dose fixed at 200 mg. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

## Injection

| 10493G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 5           | ..         | *9005.06 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

### ■ 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.

#### 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.
- 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
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. The treatment must not exceed a total of 35 cycles in a lifetime.

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

#### **Authority required**

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment - Grandfathered patients

#### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with a programmed cell death 1 (PD-1) inhibitor for this condition prior to 1 May 2018, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT prior to receiving treatment with a PD-1 inhibitor for this condition; OR
- Patient must not have been suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition prior to receiving treatment with a PD-1 inhibitor 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 the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 35 cycles in a lifetime.

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.

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 for Grandfathered patients.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Injection**

| 11330H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 6           | ..         | *9005.06 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

### **■ 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.

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

**8563**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised treatment 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 at a maximum dose of 200 mg every 3 weeks for this condition 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)**

**8543**

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 treatment for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug for this condition.

**Authority required (STREAMLINED)**

**8542**

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

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 March 2019, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy prior to initiating treatment with this drug for this condition; 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 prior to initiating treatment with this drug for this condition; 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 prior to initiating treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug 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.

**Injection**

| 11646Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 6           | ..         | *9005.06 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

▪ **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.

**Authority required (STREAMLINED)**

**8122**

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

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample; **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 tumour material, **AND**
- The treatment must not exceed a total of 7 doses at a maximum dose of 200 mg every 3 weeks for this condition 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)**

**8123**

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

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 November 2018, **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 stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **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 express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample 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 in tumour material, **AND**
- The treatment must not exceed 35 doses in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks, with this drug for this condition.

**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.

**Authority required (STREAMLINED)**

**8124**

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

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 treatment for this condition, **AND**
- The treatment must not exceed 35 doses in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks, with this drug for this condition.

**Injection**

| 11494Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                    |
|--------|-------------|-------------|------------|----------|----------|----------------------------------------------------------------|
|        | 200 mg      | 6           | ..         | *9005.06 | 40.30    | Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) |

▪ **PERTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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:

(i) a copy 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; and

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

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

## Injection

| 10267J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------|
|        | 840 mg      | ..          | ..         | *6229.80 | 40.30    | Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial) |

## ■ PERTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

### Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; OR
- Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015, **AND**
- Patient must not have received non-PBS-subsidised treatment with trastuzumab for this condition before 1 July 2014, **AND**
- Patient must not have received prior therapy with trastuzumab emtansine or lapatinib for this condition, **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.

Authority applications for treatment must be made in writing and must include a completed authority prescription form and a copy of the signed patient acknowledgement form.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

## Injection

| 10309N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                  |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------|
|        | 840 mg      | 1           | ..         | *6229.80 | 40.30    | Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial) |

## ■ PERTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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

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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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. However, short treatment breaks are permitted. A patient who has a treatment break of less than 6 weeks 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. A patient who has a treatment break of more than 6 weeks in PBS-subsidised treatment with this drug is not eligible 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

|        |             |             |            |          |          |                                                              |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------|
| 10333W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                  |
|        | 420 mg      | 3           | ..         | *3157.43 | 40.30    | Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial) |

### ■ 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).

### Injection

|       |             |             |            |          |          |                                                                   |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------|
| 4614W | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                       |
|       | 800 mg      | 7           | ..         | *2556.26 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) |
|       |             |             |            |          |          | Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)      |

### ■ RITUXIMAB

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

#### 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.

### Injection

|       |             |             |            |          |          |                                                                   |
|-------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------|
| 4613T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                       |
|       | 800 mg      | 7           | ..         | *2556.26 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) |
|       |             |             |            |          |          | Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)      |

### ■ 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.

## Injection

| 4615X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                       |
|-------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------------------|
|       | 800 mg      | 5           | ..         | *2556.26 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)<br>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial) |

## ■ 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.

## Injection

| 10179R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                       |
|--------|-------------|-------------|------------|----------|----------|-----------------------------------------------------------------------------------------------------------------------------------|
|        | 800 mg      | 11          | ..         | *2556.26 | 40.30    | Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials)<br>Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial) |

## ■ TRASTUZUMAB

### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

#### **Clinical criteria:**

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone 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**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

#### **Clinical criteria:**

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **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.

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

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

(a) a completed authority prescription form; and

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

- a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
- a copy of the signed patient acknowledgement form.

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## Injection

| 4632T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 500 mg      | ..          | ..         | *1898.01 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

### Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone 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**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

### Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **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.

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

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

(a) a completed authority prescription form; and

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

- (i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and
- (ii) a copy of the signed patient acknowledgement form.

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

## Injection

| 4650R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 1000 mg     | ..          | ..         | *3710.96 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

**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 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 a copy 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 patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**Injection**

| 10391X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 1000 mg     | ..          | ..         | *3710.96 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

▪ **TRASTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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**

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**
- 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, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**Injection**

| 10401K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 750 mg      | 3           | ..         | *2751.16 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

▪ **TRASTUZUMAB**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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**

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, **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), at 3 monthly intervals during treatment.

**Injection**

| 10423N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                   |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------|
|        | 1000 mg     | 3           | ..         | *3710.96 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial) |

## ■ 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required

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 cisplatin and capecitabine; OR
- Patient must commence treatment in combination with cisplatin 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.

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

(a) a completed authority prescription form; and

(b) a completed Metastatic (Stage IV) HER2 positive adenocarcinoma of stomach or gastro-oesophageal junction authority application form which includes confirmation that the patient has Stage IV disease and a copy of the pathology report from an Approved Pathology Authority confirming evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated in tumour material by both (i) immunohistochemistry (IHC) 2+ or IHC 3+ AND (ii) in situ hybridisation (ISH) results based on both more than 6 copies of HER2 AND the ratio of HER2: chromosome 17 being more than 2 in the same tumour tissue sample

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment

### Injection

| 10581X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|--------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 1000 mg     | ..          | ..         | *3710.96 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

**Note** No increase in the maximum quantity or number of units may be authorised with one exception: where a patient has a break in therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose up to a maximum of 1000 mg.

**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

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

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 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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

### Injection

| 10588G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                           |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------|
|        | 750 mg      | 3           | ..         | *2751.16 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

- Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Locally advanced HER2 positive breast cancer  
Treatment Phase: Continuing treatment (weekly regimen)

### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

### Authority required

Early HER2 positive breast cancer  
Treatment Phase: Continuing treatment (weekly regimen)

### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

## Injection

| 4639E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 250 mg      | 9           | ..         | *1044.86 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

## ■ TRASTUZUMAB

- Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Authority applications for new loading doses may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Locally advanced HER2 positive breast cancer  
Treatment Phase: Continuing treatment (3 weekly regimen)

### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
  - The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
  - Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
- Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

**Authority required**

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

**Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
  - The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
  - Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
- Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

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

**Injection**

| 4703M | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                         |
|-------|-------------|-------------|------------|----------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 750 mg      | 3           | ..         | *2751.16 | 40.30    | Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)<br>Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)<br>Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) |

▪ **TRASTUZUMAB EMTANSINE**

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will be authorised.

**Authority required**

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; OR
- Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015; OR
- Patient must have received PBS-subsidised lapatinib for this condition before 1 July 2015, **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.

Authority applications for treatment must be made in writing and must include a completed authority prescription form and a copy of the signed patient acknowledgement form.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
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**
- 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) a copy 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) a copy of the signed patient acknowledgement form;
  - (iii) dates of treatment with trastuzumab and pertuzumab; and
  - (iv) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab; or
  - (v) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during 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.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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 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 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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

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.

**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**

| 10282E | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                    |
|--------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------------------------------|
|        | 450 mg      | 8           | ..         | *7642.94 | 40.30    | Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)<br>Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial) |

### ***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.

### **Injection**

| 10691Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                              |
|--------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------|
|        | 18 mg       | 140         | ..         | *806.56 | 40.30    | Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) |

#### **■ 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.

**Injection**

| 4371C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                              |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------------------------------------------|
|       | 18 mg       | 89          | ..         | *806.56 | 40.30    | Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) |

▪ **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:

- at least a 50% reduction in bone marrow plasma cells; or
- no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
- 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
- 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**

| 4712B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                            |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 11          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

▪ **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.

**Injection**

| 4725Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                        |
|-------|-------------|-------------|------------|----------|----------|----------------------------------------------------|
|       | 3000 mcg    | 11          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)   |
|       |             |             |            |          |          | Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

**■ BORTEZOMIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7992**

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, **AND**
  - Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.
- Details of the histological diagnosis of multiple myeloma must be documented in the patient's medical records.

**Injection**

| 4732C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                      |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------|
|       | 3000 mcg    | 15          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 1 mg injection, 1 vial) |
|       |             |             |            |          |          | Velcade [JC] (bortezomib 3 mg injection, 1 vial) |

**■ 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 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.

**Injection**

| 4429D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                          |
|-------|-------------|-------------|------------|----------|----------|------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 19          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 1 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3 mg injection, 1 vial) |

▪ **BORTEZOMIB**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7963**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- Patient must be ineligible for high dose chemotherapy, **AND**
- Patient must not be receiving 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)**

**7984**

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- Patient must have severe acute renal failure, **AND**
- Patient must require dialysis; OR
- Patient must be at high risk of requiring dialysis in the opinion of a nephrologist, **AND**
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must not be receiving 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.

## Injection

| 4403R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                      |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------|
|       | 3000 mcg    | 31          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 1 mg injection, 1 vial) |
|       |             |             |            |          |          | Velcade [JC] (bortezomib 3 mg injection, 1 vial) |

## ■ 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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

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
- (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**

| 4706Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                            |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 15          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

▪ **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 of the difference between involved free light chain and uninvolved free light chain; or

- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

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

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

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

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

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.

## Injection

| 4713C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                            |
|-------|-------------|-------------|------------|----------|----------|--------------------------------------------------------------------------------------------------------|
|       | 3000 mcg    | 15          | ..         | *1341.15 | 40.30    | Velcade [JC] (bortezomib 3 mg injection, 1 vial)<br>Velcade [JC] (bortezomib 3.5 mg injection, 1 vial) |

## ■ 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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

### 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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

**Authority required**

Multiple myeloma

Treatment Phase: Grandfathering

**Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 January 2018, **AND**
- Patient must have a documented histological diagnosis, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have had documented progressive disease after at least one prior therapy prior to commencing 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**
- Patient must have undergone or be ineligible for a stem cell transplant, **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 of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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

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**

| 11229B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$  | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                       |
|--------|-------------|-------------|------------|----------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | 120 mg      | 17          | ..         | *2622.94 | 40.30    | Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial)<br>Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial)<br>Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial) |

▪ **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 | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------|
|        | 3 mg        | 13          | ..         | *805.06 | 40.30    | Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial) |

▪ **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.

**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**

| 11212D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                     |
|--------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------|
|        | 3 mg        | 7           | ..         | *805.06 | 40.30    | Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial) |

▪ **IRINOTECAN**

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

**Injection**

| 4451G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | 800 mg      | 11          | ..         | *149.94 | 40.30    | Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)<br>Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>IRINOTECAN ACT [JU] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>IRINOTECAN ACT [JU] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)<br>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)<br>Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)<br>Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)<br>Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) |

▪ **TOPOTECAN**

**Authority required (STREAMLINED)**

**6238**

Advanced metastatic ovarian cancer

**Clinical criteria:**

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

**Injection**

| 4617B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                       |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------|
|       | 3500 mcg    | 17          | ..         | *117.14 | 40.30    | Hycamtin [SZ] (topotecan 4 mg injection, 5 vials) |



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# Related Pharmaceutical Benefits for Public Hospital use

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## ALIMENTARY TRACT AND METABOLISM

## ANTIEMETICS AND ANTINAUSEANTS

### ANTIEMETICS AND ANTINAUSEANTS

#### Serotonin (5HT<sub>3</sub>) 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.

#### granisetron 2 mg tablet, 1

| 5898K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 2           | ..          | ..         | *16.58  | 17.83    | Kytril [IX]                 |

#### granisetron 3 mg/3 mL injection, 3 mL ampoule

| 5899L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                   | Brand Name and Manufacturer        |
|-------|-------------|-------------|------------|---------|----------|---------------------------------------------------------------|------------------------------------|
|       | 1           | ..          | ..         | 1.92    | 3.17     | <sup>a</sup> Granisetron-AFT [AE]<br><sup>a</sup> Kytril [IX] | <sup>a</sup> Granisetron Kabi [PK] |

#### 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, **AND**
- The treatment must be in combination with 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; 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**

|        |             |             |            |         |          |                             |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
| 10714X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|        | ±1          | 5           | ..         | 97.16   | 40.30    | Akynzeo [MF]                |

**■ 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**

|       |             |             |            |         |          |                             |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
| 5848T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|       | ±1          | ..          | ..         | 80.78   | 40.30    | Zofran syrup 50 mL [AS]     |

**ondansetron 8 mg tablet, 4**

|       |             |             |            |         |          |                                                                                                                                                          |                                                                                                                                        |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 5968D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                              | Brand Name and Manufacturer                                                                                                            |
|       | 1           | ..          | ..         | 5.35    | 6.60     | <sup>a</sup> APO-Ondansetron [TX]<br><sup>a</sup> Ondansetron APOTEX [GX]<br><sup>a</sup> Ondansetron Mylan Tablets [AF]<br><sup>a</sup> Onsetron 8 [ZP] | <sup>a</sup> Ondansetron AN [EA]<br><sup>a</sup> Ondansetron-DRLA [RZ]<br><sup>a</sup> Ondansetron SZ [HX]<br><sup>a</sup> Zofran [AS] |

**ondansetron 4 mg tablet, 4**

|       |             |             |            |         |          |                                                                                                                                                          |                                                                                                                                        |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 5967C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                                                              | Brand Name and Manufacturer                                                                                                            |
|       | 1           | ..          | ..         | 3.41    | 4.66     | <sup>a</sup> APO-Ondansetron [TX]<br><sup>a</sup> Ondansetron APOTEX [GX]<br><sup>a</sup> Ondansetron Mylan Tablets [AF]<br><sup>a</sup> Onsetron 4 [ZP] | <sup>a</sup> Ondansetron AN [EA]<br><sup>a</sup> Ondansetron-DRLA [RZ]<br><sup>a</sup> Ondansetron SZ [HX]<br><sup>a</sup> Zofran [AS] |

**■ 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/2 mL injection, 2 mL ampoule**

|       |             |             |            |         |          |                                          |                             |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------|-----------------------------|
| 5971G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer              | Brand Name and Manufacturer |
|       | 1           | ..          | ..         | .32     | 1.57     | <sup>a</sup> Ondansetron Alphapharm [AF] | <sup>a</sup> Onsetron [ZP]  |

**ondansetron 8 mg/4 mL injection, 4 mL ampoule**

|       |             |             |            |         |          |                                          |                             |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------|-----------------------------|
| 5972H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer              | Brand Name and Manufacturer |
|       | 1           | ..          | ..         | .51     | 1.76     | <sup>a</sup> Ondansetron Alphapharm [AF] | <sup>a</sup> Onsetron [ZP]  |

**■ 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.

**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 orally disintegrating tablet, 4**

|       |             |             |            |         |          |                                      |                                         |
|-------|-------------|-------------|------------|---------|----------|--------------------------------------|-----------------------------------------|
| 5857G | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer          | Brand Name and Manufacturer             |
|       | 1           | ..          | ..         | 3.41    | 4.66     | <sup>a</sup> Ondansetron AN ODT [EA] | <sup>a</sup> Ondansetron Mylan ODT [AF] |

<sup>a</sup> Ondansetron ODT-DRLA [RZ] <sup>a</sup> Ondansetron ODT GH [GQ]<sup>a</sup> Ondansetron SZ ODT [HX]**ondansetron 8 mg wafer, 4**

| 5970F | Max. Amount | No. of Rpts | Premium \$        | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer    |
|-------|-------------|-------------|-------------------|---------|----------|--------------------------------|
|       | 1           | ..          | <sup>B</sup> 2.28 | 7.63    | 6.60     | <sup>a</sup> Zofran Zydys [AS] |

**ondansetron 4 mg wafer, 4**

| 5969E | Max. Amount | No. of Rpts | Premium \$        | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer    |
|-------|-------------|-------------|-------------------|---------|----------|--------------------------------|
|       | 1           | ..          | <sup>B</sup> 2.28 | 5.69    | 4.66     | <sup>a</sup> Zofran Zydys [AS] |

**ondansetron 8 mg orally disintegrating tablet, 4**

| 5858H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                                                                            | Brand Name and Manufacturer                                                     |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
|       | 1           | ..          | ..         | 5.35    | 6.60     | <sup>a</sup> Ondansetron AN ODT [EA]<br><sup>a</sup> Ondansetron ODT-DRLA [RZ]<br><sup>a</sup> Ondansetron SZ ODT [HX] | <sup>a</sup> Ondansetron Mylan ODT [AF]<br><sup>a</sup> Ondansetron ODT GH [GQ] |

**■ 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-HT<sub>3</sub> antagonists.**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.

**palonosetron 250 microgram/5 mL injection, 5 mL vial**

| 5853C | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 1           | ..          | ..         | 32.64   | 33.89    | Aloxi [MF]                  |

**■ TROPISETRON****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.

**tropisetron 5 mg/5 mL injection, 5 mL ampoule**

| 5987D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 1           | ..          | ..         | 4.57    | 5.82     | Tropisetron-AFT [AE]        |

***Other antiemetics*****■ 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.**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 (5HT<sub>3</sub>) 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 (5HT<sub>3</sub>) 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; 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 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**

| 11103J | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 5           | ..         | 97.16   | 40.30    | Emend IV [MK]               |

■ **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

■ **ANTINEOPLASTIC AGENTS**

**OTHER ANTINEOPLASTIC AGENTS**

*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**

| 10741H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 6           | ..         | 2265.49 | 40.30    | Mabthera SC [RO]            |

■ **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.

## rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

| 10708N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 5           | ..         | 2265.49 | 40.30    | Mabthera SC [RO]            |

### ▪ RITUXIMAB

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

#### 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

| 10720F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 7           | ..         | 2265.49 | 40.30    | Mabthera SC [RO]            |

### ▪ 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

| 10710Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 11          | ..         | 2265.49 | 40.30    | Mabthera SC [RO]            |

### ▪ 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

#### Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

#### **Clinical criteria:**

- Patient must have previously received treatment with PBS-subsidised trastuzumab, **AND**
  - The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
  - Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
- Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

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

#### trastuzumab 600 mg/5 mL injection, 5 mL vial

| 10743K | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 3           | ..         | 1667.10 | 40.30    | Herceptin SC [RO]           |

#### ■ TRASTUZUMAB

##### Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

##### Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
  - Patient must have undergone 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**
  - Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.
- HER2 positivity must be demonstrated by in situ hybridisation (ISH).

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

##### Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

##### Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **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.

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

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

(a) a completed authority prescription form; and

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

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

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### trastuzumab 600 mg/5 mL injection, 5 mL vial

| 10744L | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | ..          | ..         | 1667.10 | 40.30    | Herceptin SC [RO]           |

#### ■ TRASTUZUMAB

**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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**
- 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 a copy 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 patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

| 10811B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | ..          | ..         | 1667.10 | 40.30    | Herceptin SC [RO]           |

**■ TRASTUZUMAB**
**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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**

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**
- 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, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

| 10817H | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 3           | ..         | 1667.10 | 40.30    | Herceptin SC [RO]           |

**■ TRASTUZUMAB**
**Note** No applications for increased maximum quantities will be authorised.

**Note** No applications for increased repeats will 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**

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, **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), at 3 monthly intervals during treatment.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

| 10829Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|--------|-------------|-------------|------------|---------|----------|-----------------------------|
|        | 1           | 3           | ..         | 1667.10 | 40.30    | Herceptin SC [RO]           |

**■ IMMUNOSTIMULANTS**
**IMMUNOSTIMULANTS**
*Interferons*

## ■ INTERFERON ALFA-2A

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

**Authority required (STREAMLINED)**

**6678**

Myeloproliferative disease

**Clinical criteria:**

- Patient must have excessive thrombocytosis.

### interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

| 5998Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 5           | 4           | ..         | *363.00 | 40.30    | Roferon-A [RO]              |

## ■ INTERFERON ALFA-2A

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

**Authority required (STREAMLINED)**

**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 9 million units/0.5 mL injection, 0.5 mL syringe

| 5949D | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 5           | 5           | ..         | *363.00 | 40.30    | Roferon-A [RO]              |

### interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

| 5946Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 15          | 5           | ..         | *363.15 | 40.30    | Roferon-A [RO]              |

## ■ INTERFERON ALFA-2A

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

**Authority required (STREAMLINED)**

**6662**

Hairy cell leukaemia

**Authority required (STREAMLINED)**

**6678**

Myeloproliferative disease

**Clinical criteria:**

- Patient must have excessive thrombocytosis.

### interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

| 5945X | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 15          | 4           | ..         | *363.15 | 40.30    | Roferon-A [RO]              |

### Other immunostimulants

## ■ 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

| 5902P | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 1           | 1           | ..         | 399.49  | 40.30    | OncoTICE [MK]               |

## ■ VARIOUS

## ■ ALL OTHER THERAPEUTIC PRODUCTS

### ALL OTHER THERAPEUTIC PRODUCTS

#### Detoxifying agents for antineoplastic treatment

## ■ FOLINIC ACID

### folinic acid 1 g/100 mL injection, 100 mL vial

| 5863N | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 1           | 1           | ..         | 35.98   | 37.23    | Calcium Folate Ebewe [SZ]   |

**folinic acid 300 mg/30 mL injection, 30 mL vial**

| 5870Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer            | Brand Name and Manufacturer                                |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------|------------------------------------------------------------|
|       | 4           | 1           | ..         | *42.12  | 40.30    | <sup>a</sup> Calcium Folate Ebewe [SZ] | <sup>a</sup> Leucovorin Calcium (Hospira Pty Limited) [PF] |

▪ **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**

| 5890B | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                |
|-------|-------------|-------------|------------|---------|----------|------------------------------------------------------------|
|       | 10          | 2           | ..         | *38.90  | 40.15    | <sup>a</sup> Leucovorin Calcium (Hospira Pty Limited) [PF] |

**folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules**

| 1899Y | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                     |
|-------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------|
|       | 1           | 2           | ..         | 38.90   | 40.15    | <sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF] |

▪ **FOLINIC ACID**

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

**folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules**

| 1904F | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                                     |
|-------|-------------|-------------|------------|---------|----------|-----------------------------------------------------------------|
|       | 1           | 1           | ..         | 43.80   | 40.30    | <sup>a</sup> Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF] |

**folinic acid 100 mg/10 mL injection, 10 mL vial**

| 5886T | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer            |
|-------|-------------|-------------|------------|---------|----------|----------------------------------------|
|       | 10          | 1           | ..         | *43.80  | 40.30    | <sup>a</sup> Calcium Folate Ebewe [SZ] |

▪ **FOLINIC ACID****Restricted 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**

| 5904R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer                   |
|-------|-------------|-------------|------------|---------|----------|-----------------------------------------------|
|       | 1           | ..          | ..         | 76.00   | 40.30    | Leucovorin Calcium (Hospira Pty Limited) [PF] |

▪ **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**

| 5961R | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 1           | 5           | ..         | 150.63  | 40.30    | Uromitexan [BX]             |

**mesna 400 mg/4 mL injection, 15 x 4 mL ampoules**

| 5960Q | Max. Amount | No. of Rpts | Premium \$ | DPMA \$ | MRVSN \$ | Brand Name and Manufacturer |
|-------|-------------|-------------|------------|---------|----------|-----------------------------|
|       | 1           | 5           | ..         | 66.52   | 40.30    | Uromitexan [BX]             |

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# Index of Manufacturers' Code

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| <b>Code</b> | <b>Manufacturer</b>                         |
|-------------|---------------------------------------------|
| <b>AE</b>   | AFT Pharmaceuticals (AU) Pty Ltd            |
| <b>AF</b>   | Alphapharm Pty Ltd                          |
| <b>AN</b>   | Amgen Australia Pty Limited                 |
| <b>AS</b>   | Aspen Pharmacare Australia Pty Limited      |
| <b>BQ</b>   | Bristol-Myers Squibb Australia Pty Ltd      |
| <b>BX</b>   | Baxter Healthcare Pty Limited               |
| <b>EA</b>   | Amneal Pharmaceuticals Pty Ltd              |
| <b>EI</b>   | Eisai Australia Pty Ltd                     |
| <b>FB</b>   | Pierre Fabre Australia Pty Ltd              |
| <b>FF</b>   | Phebra Pty Ltd                              |
| <b>GQ</b>   | Generic Health Pty Ltd                      |
| <b>GX</b>   | Apotex Pty Ltd                              |
| <b>HX</b>   | Sandoz Pty Ltd                              |
| <b>IX</b>   | Clinect Pty Ltd                             |
| <b>JC</b>   | Janssen-Cilag Pty Ltd                       |
| <b>JU</b>   | Juno Pharmaceuticals Pty Ltd                |
| <b>LR</b>   | Cipla Australia Pty Ltd                     |
| <b>LY</b>   | Eli Lilly Australia Pty Ltd                 |
| <b>MF</b>   | Mundipharma Pty Limited                     |
| <b>MK</b>   | Merck Sharp & Dohme (Australia) Pty Ltd     |
| <b>OA</b>   | Orphan Australia Pty Ltd                    |
| <b>OC</b>   | Accord Healthcare Pty Ltd                   |
| <b>OD</b>   | Accord Healthcare Pty Ltd                   |
| <b>OE</b>   | Omegapharm Pty Ltd                          |
| <b>PF</b>   | Pfizer Australia Pty Ltd                    |
| <b>PK</b>   | Fresenius Kabi Australia Pty Limited        |
| <b>QY</b>   | Pro Pharmaceuticals Group Pty Ltd           |
| <b>RA</b>   | Sun Pharma ANZ Pty Ltd                      |
| <b>RO</b>   | Roche Products Pty Ltd                      |
| <b>RZ</b>   | Dr Reddy's Laboratories (Australia) Pty Ltd |
| <b>SE</b>   | Servier Laboratories (Aust.) Pty Ltd        |
| <b>SG</b>   | Merck Serono Australia Pty Ltd              |
| <b>SW</b>   | sanofi-aventis Australia Pty Ltd            |
| <b>SZ</b>   | Sandoz Pty Ltd                              |
| <b>TB</b>   | Teva Pharma Australia Pty Limited           |
| <b>TK</b>   | Takeda Pharmaceuticals Australia Pty Ltd    |
| <b>TS</b>   | Specialised Therapeutics Australia Pty Ltd  |
| <b>TX</b>   | Apotex Pty Ltd                              |
| <b>ZP</b>   | Medis Pharma Pty Ltd                        |

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